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EMBRYONIC STEM CELL RESEARCH: EXPLORING THE CONTROVERSY

HEARING

BEFORE THE

SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

SEPTEMBER 29, 2004

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

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EMBRYONIC STEM CELL RESEARCH: EXPLORING THE CONTROVERSY

WEDNESDAY, SEPTEMBER 29, 2004

U.S. SENATE,
SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2 p.m. in room SR–253, Russell Senate Office Building, Hon. Sam Brownback, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. SAM BROWNBACK, U.S. SENATOR FROM KANSAS

Senator BROWNBACK. Call the hearing to order. Thank you all for joining us today. If we could have the first two witnesses please come up to the table, Senator Wyden and I have opening statements and then we'll go with the witnesses.

We have two votes, starting at 2:15. We'll try to get as far along as we can before we take a break. I doubt if we can, two votes, back to back. But we want to move as far as we can.

Calling this hearing, the Senate Subcommittee on Science, Technology, and Space, to order. We had a hearing a couple of months ago on adult stem cell advances, and I stated at that time that we'd be holding one on embryonic stem cell. And that's what this hearing is about today. And I appreciate all of you being here.

As Chair of the Science Subcommittee, I called this hearing to examine the ethics and scientific advances of 20 years of embryonic stem cell research. The first panel of witnesses will discuss the ethics of embryonic stem cell research, and the second panel will examine the scientific advances of embryonic stem cell research.

It's alleged that human embryonic stem cells are a veritable fount of cures for those afflicted with disease; however, to date, I am unaware of one person being cured from either private or federally funded human embryonic stem cell research. In July, this Subcommittee heard testimony from real Parkinson's and spinal injury patients whose lives have been dramatically improved by adult stem cell treatments. To date, 45 diseases and medical conditions in humans have been treated with adult stem cells, such as those taken from umbilical cord blood and placenta tissue where there are no ethical or moral problems. We need to put finite Federal dollars where they will make the most difference and do no harm.

We will discuss the issues of cures on the second panel. First, we will start with the basic science.

Science is very clear. Human embryos are living human beings at their earliest stages of development. A one cell zygote, whether created through fertilization or cloning, is human. We all agree it is alive and it is a human; the question seems to be, is it a life?

Science is about the pursuit of truth in the service of mankind, and science tells us that the human embryo, whether created naturally or in a petri dish, is an organism of the species homo sapiens, a human being. To obtain human embryonic stem cells, human embryos must be destroyed. Is it right to destroy these human embryos, human beings, at the youngest stages of life, in order to collect their stem cells?

I've called this hearing largely because I'm troubled that science is being distorted in the debate over human embryonic stem cells and that some are even casting doubt on the scientific fact that young human embryos are human lives. Make no mistake, this issue involves both biology and ethics. That's why we have two separate expert panels to discuss each of these issues separately.

Let us be clear, when it is said that human life begins at the embryonic stage, biology is being discussed—not ideology, belief, or ethics. When it is said that no human life, young or old, should be taken, we are discussing the traditional Western ethic that have made our nation great.

A human embryo is, biologically speaking, a young human life. It is not a scientific statement to assert that it is not a life or that it is a potential life. In fact, to assert that a human embryo is not a human life is a belief unsupported by the facts. To assert that a human embryo is not a human life is inaccurate.

The topic of human embryonic stem cell research is controversial because it touches on the beginnings of human life, the value of human life, and respect for human life. Human embryonic stem cells force us to consider the fundamental questions about the beginnings of human life. And for that, we can be thankful. Human adult and non-embryonic stem cells that are noncontroversial are yielding results at no cost to any living human beings.

We hope to have a good discussion on this topic today. We look forward to the panel and the presentations.

And I turn to my Ranking Member for an opening statement.

STATEMENT OF HON. RON WYDEN,
U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you very much, Mr. Chairman. As you know, you and I agree on so many issues in the area of science and technology and international affairs and others. And this is one where I think even a casual observer of what goes on in this Subcommittee is aware that this is one where we do have diametrically opposed views. And I want to say, as we go to today's hearing, I want to commend you for your fairness, because we have always debated these issues in an open and straightforward kind of fashion, and you've always been eminently fair, and I thank you for it. And I know we're going to have a good debate today.

Just, if I might, Mr. Chairman, a few comments. First, I'd like to put into the record an article from the Washington Post on Sunday by Rick Weiss, a reporter who specializes in this area, and it discusses how human embryonic stem cells, through some new ex-

periments that we have seen with the cells, are producing some very significant results. One of the reports discussed in the article discusses how stem cells, for the first time, are now a cell crucial to vision. They can become a cell that is crucial to this area that is of concern to so many patients. I would just ask that that be made a part of the record.

Senator BROWNBACK. Without objection.

[The information referred to follows:]

The Washington Post—September 26, 2004

TWO STUDIES BOLSTER STEM CELLS' USE IN FIGHTING DISEASE

By Rick Weiss

The prospect of using human embryonic stem cells to treat disease appears a small step closer as the result of two new experiments with the cells, which are mired in political controversy because they are derived from human embryos.

In one report released yesterday, researchers showed that the versatile cells can serve as "biological pacemakers," correcting faulty heart rhythms when injected into the failing hearts of pigs.

In another report, scientists demonstrated for the first time that stem cells can become a cell crucial to vision. Many doctors believe that several vision-destroying diseases could be fought by transplanting these cells directly into the eyes.

Human embryonic stem cells, derived from five-day-old embryos, have the biological potential to morph into virtually all of the 200 or so kinds of cells in the body. Researchers are racing to learn how to direct them to develop into specific types of cells that can be transplanted into failing organs. It is an approach that could launch a new era of regenerative medicine—but only if the cells prove capable of integrating into existing organs and functioning normally there.

Izhak Kehat and Lior Gepstein of the Technion-Israel Institute of Technology in Haifa and their colleagues sought to test that capacity with stem cells that were growing into heart muscle cells.

The team started with masses of stem cells growing in laboratory dishes, from which they isolated those few that were spontaneously developing into heart cells.

They were easy to spot: They were the ones that were pulsing in unison, as heart cells are apt to do.

In one experiment, the scientists isolated small balls of the human cells—each ball about the size of the head of a pin, or about 1 million cells—and placed that little mass into a lab dish with rat heart cells.

The cells of each species, rat and human, beat at different rates at first. Within 24 hours of living together, however, the combined masses of cells coordinated their pulsing into a single rhythm.

"At least in the dish, they integrated structurally, mechanically and electrically," Gepstein said.

But could stem-derived heart cells help set the pace of a heart in a live animal?

To find out, the team threaded a probe into the hearts of 13 pigs and made a small burn in the area that regulates the heart beat, causing a permanent severe slowing of those animals' heart rates. The injury mimicked a human heart rhythm disorder that could be caused by disease or a small heart attack.

Then they injected about 100,000 of their human embryo-derived heart cells into the damaged pig hearts. Eleven of the 13 returned to faster heart rates, the team reported in yesterday's advanced online edition of *Nature Biotechnology*. There was no improvement in control animals that did not receive the cells.

"It's not like tomorrow people are going to be waiting in line for biological pacemakers," Gepstein said. "But we were happy to see after a few days a new rhythm arose," providing what he called "proof of principle."

A second report—appearing in the fall issue of the journal *Cloning and Stem Cells*—describes the first documented growth of retinal pigment epithelial cells, or RPE cells, from human embryonic stem cells.

RPE cells, which are related to nerve cells, live inside the eye and provide essential "housekeeping" duties for the rods and cones—the light-sensitive cells in the retina. RPE cells scavenge the retinal area for cellular debris, sucking old material up like little vacuum cleaners. And they secrete substances that aid in tissue repair within the eye.

The loss of RPE cells in middle and old age is a major cause of age-related vision loss, including macular degeneration. That disease is the leading cause of blindness

in people older than 60, affecting 30 million people worldwide. Doctors have begun to experiment with RPE cell transplants into people's eyes, but the approach has been plagued by problems—including an inadequate supply of cells.

In experiments led by Irina Klimanskaya and Robert Lanza of Advanced Cell Technology in Worcester, Mass., human embryonic stem cells grown in lab dishes under certain conditions spontaneously became RPE cells, offering a possible solution to the supply problem.

Moreover, the ACT system involves no animal cells or products—a feature the Food and Drug Administration has said will be important as it considers granting permission to test stem cell-derived cells in people.

Lanza said the company hopes to complete transplant studies in large animals during the next year, after which it will apply for permission to test the cells' safety and therapeutic value in the eyes of people with RPE-related vision loss.

Not all stem cell colonies worked equally well, Lanza noted, touching on a hot area of political debate. Six of the colonies—those developed by Harvard researcher Douglas Melton with private funds—"worked like a charm," Lanza said, as did two colonies developed by ACT.

But the three colonies developed by a Wisconsin team—among the few approved by President Bush for study with Federal dollars—worked only "very reluctantly," Lanza said. Bush has banned Federal funding for research on newly derived stem cell lines in order not to encourage the destruction of human embryos, but Lanza said his work shows that policy is short-sighted.

"It's becoming clear that each colony is different and can do different tricks," Lanza said. "To limit federally funded research to just a handful of lines is a mistake."

Senator WYDEN. Mr. Chairman, as we all know, the President, a number of years ago, limited Federal-funded research in this area to what amounts to literally just a few more than existing cell lines. Now only 21 of the initial 78 stem cell lines seem to be available to researchers, and it's recently been reported—and I'd ask that this article be made a part of the record, as well—that more than a hundred new lines have been developed since the President's cutoff date, and now we have many that are much better suited for research. And I'd like an article that addresses that point to be made a part of the record, as well.

Senator BROWNBACK. Without objection.

[The information referred to follows:]

USA Today—August 17, 2004

NOBEL LAUREATE DECRIES LIMITS ON STEM CELL RESEARCH

By Katharine Webster, Associated Press

MANCHESTER, N.H.—A Nobel laureate in medicine says the Bush administration's limits on funding for embryonic stem cell research effectively have stopped the clock on American scientists' efforts to develop treatments for a host of chronic, debilitating diseases.

"This is a topic of science and medicine, but it's a topic that's become embroiled in politics," H. Robert Horvitz, a Massachusetts Institute of Technology biologist, said Monday at an Elliot Hospital forum organized by Democratic presidential nominee John Kerry's campaign.

Embryonic stem cells are cultured from leftover, 5-day-old embryos created for infertility treatment. They would be discarded if not used for research, with the permission of the infertile couple, Horvitz said. Embryonic stem cell lines were first successfully cultured in 1998.

Three years ago, President Bush—concerned that harvesting the cells required the destruction of human embryos—limited federally funded research to a few dozen existing cell lines.

Only 21 of the initial 78 stem cell lines are available to researchers now. Scientists say more than 100 new lines have been developed since Bush's cutoff date, some of which are much better suited for research.

Horvitz also said researchers need access to diverse embryonic stem cell lines so they can develop treatments that are good genetic matches for patients of different races and ethnic backgrounds.

Horvitz, whose father died of Lou Gehrig's disease, said research and treatments derived from embryonic stem cells have the potential to help future sufferers of brain diseases, diabetes, heart disease, multiple sclerosis and cancer.

"Some people who oppose embryonic stem cell research say the problem of curing these diseases is very far in the future," he said. "My response is: Let's get on with it."

Embryonic stem cell research will not yield quick results in some areas, but in others, treatments could be available within a decade, he said.

"In 10 years, a child with a spinal cord injury may be able to walk—if we start now," the 2002 Nobel Prize winner said.

Ann McLane Kuster, vice-chairwoman of New Hampshire Women for Kerry, made an emotional appeal for lifting the restrictions. Her mother, former Republican state Sen. Susan McLane, suffers from Alzheimer's and no longer can stand or speak, she said.

"Advances in stem cell research are being held hostage by the extreme right," she said. "This is emotional. This is about our future, our children, our parents, and we cannot let ideology determine our future."

She said it is a bipartisan issue, noting that U.S. Reps. Charles Bass and Jeb Bradley, both New Hampshire Republicans, support lifting the restrictions.

Speaking for the Bush campaign at a muddy baseball field near the hospital, state Rep. Rogers Johnson, R-Stratham, accused the Kerry campaign of "using stem cell research for purely political gain."

"There are people leading with their hearts on this issue, and I feel for them," he said. But, "Alzheimer's is not likely to be something you can cure using embryonic stem cells."

Because treatments are far in the future, there is no harm in proceeding cautiously with a debate on the ethical issues, he said.

Johnson also noted that Bush was the first president to authorize any Federal spending on stem cell research. However, most of the money has gone to research on adult stem cells, not embryonic cells.

Senator WYDEN. Perhaps my biggest single concern at this point, Mr. Chairman, is the fact that because all over the country our citizens are so frustrated with the restrictions on research at the Federal level, we now see states—California is the latest—essentially taking off on their own. They are simply saying, as the result of enormous grassroots pressure in various parts of the country, that they're not going to abide by the Federal Government's policy of inaction and stonewalling on this issue, and they're, in effect, going to go to their constituents and start their own program.

And what troubles me is, as a result of these Federal restrictions—in terms of funding, in particular—we are going to see states all over America essentially go off and do their own thing. And, at a minimum, I think we are going to end up with what amounts to a crazy quilt of rules and certainly ethical kinds of standards, at a minimum. We'll see California take one approach, another area—New Jersey will perhaps take another approach; we'll have a set of rules at the Federal level.

And what the scientists have been telling us, what the NIH scientists who have been writing in on this have said, that it's important that there be one ethical standard. We need to have one ethical standard so that it is clear that we can address some of the concerns that we're going to hear about today. I know they're heartfelt. Witnesses who have a different view of this issue than I do are going to raise legitimate ethical concerns. We do need one strong Federal ethical standard, rather than this mishmash, a kind of crazy quilt of rules that I think we're going to end up with, and end up very quickly with, as a result of the frustration that we are seeing around this country.

So this is a timely hearing. It's timely because of the new evidence reported about the potential for human embryonic stem cells just this week. It's important because we are seeing that there are a lot of new stem cell lines that are available since the President's cutoff date. And it is timely because, once again, with this California ballot measure, we are going to see the consequences where we have what amounts to, I think, sort of, scientific chaos as people try to figure out what the rules are in an area that really cries out for a responsible, thoughtful approach that ensures that the research can go forward that is of such promise for our citizens, while, at the same time, addressing the ethical concerns that you and a number of our witnesses appropriately highlight.

So I look forward to working with you today, Mr. Chairman, and in the days ahead. I suspect that this will not be our last hearing on the subject, and know that you will, as you have been in the past, be very fair.

Senator BROWNBACK. Thanks. And thank you for how you've always conducted yourself in these discussions, and I appreciate that greatly.

And I hope today can be a good hearing and discussion of the issues, where there can be a candid discussion of the thoughts, both ethical and scientific, as we really try to take an in-depth look at the overall issue. And I know you share the desire to do that, as well.

We're going to go ahead with the presentations and start, even though we're likely to have interruption with a vote taking place.

The first panel is an ethics panel. We'll have Dr. Laurie Zoloth. She's the Director of Bioethics, Center for Genetic Medicine, Professor of Medical Ethics and Humanities, and a Professor of Religion at Northwestern University in Chicago. Delighted to have you here. And Mr. Richard Doerflinger, Deputy Director of the U.S. Conference of Catholic Bishops here in Washington, D.C. Mr. Doerflinger, delighted to have you here.

Dr. Zoloth, please proceed with your presentation, and then we'll go with Mr. Doerflinger, and we'll have questions.

STATEMENT OF LAURIE ZOLOTH, PH.D, PROFESSOR, BIOETHICS AND RELIGION, MEDICAL HUMANITIES AND BIOETHICS PROGRAM AND DIRECTOR OF BIOETHICS, CENTER FOR GENETIC MEDICINE, FEINBERG SCHOOL OF MEDICINE, NORTHWESTERN UNIVERSITY

Dr. ZOLOTH. Mr. Chairman, Mr. Wyden, I want to thank the Committee for asking us to testify why my university supports human embryonic stem cell research. It's part of our broad commitment to the translation of basic medical science into healing. Serving the public's health is the core moral gesture of the medicine we teach. Basic research is free speech that must both be funded and regulated in full view of the public.

As I wrote this testimony, my tenth grader was also writing a speech about stem cells. It's a big topic in our democracy. And, like each of you, I worry about the sort of moral universe I will leave to my children.

I've listened carefully to the scientific researchers, and I'm convinced by the growing body of evidence both that these cells can

be made into some useful tissue, and that research on them can explain the nature of how disease works at the cellular level, and this is stunningly important. If even some of what we are told to hope for is correct, then how we think about illness and injury will be transformed.

So what ethical considerations are a barrier to the full funding of this science? There are three: how we get the cell, where we get the cell, and what we use them for.

First is the moral status of the human blastocyst and our duties toward it. Second is the process that researchers need to get eggs and sperm donated fairly and safely, and our duties to donors. Finally, if researchers can find successful therapies, how will only good goals of medicine be pursued, and access to the cures be fair?

I think we can agree about the duties of justice and science and how we must treat human research subjects, but we cannot come to an agreement on what most divides us here today: when human life begins. This is a profoundly religious question in a profoundly religious country profoundly dedicated to the proposition that our freedom to faithfully interpret our faith is the core of American life.

For nearly all Jews, most Muslims, many Buddhists, many Protestants, it is not only permissible to use human blastocysts to create stem cell lines, it is morally imperative—it must be done if it can lead to saving lives.

As an orthodox Jew, I understand the blastocysts made in the lab at the very first stages of division is, at that moment, a cluster of cells, and does not have the moral status of a human child. It lacks a mother's womb, its existence is only theoretical without this, and it is far before our tradition considers it a human person.

I respect that there is a difference in theology. And while I understand your passion and the conviction of those for whom the blastocyst is a person from the moment of fertilization, I do not believe that it is; and it is a matter of faith for me, as well. My passion and my conviction are toward the suffering of the one I see in need. For Jews, the commandant to attend to the suffering is core to my faith. Jewish organizations, from Hadassah to the Rabbinic boards of Jewish organizations, speak in one voice on this matter: stem cell research is an activity of *pikuach nefesh,* saving and healing broken lives, and of *tikkun olam,* repairing an unfinished natural world.

What are you to do, as leaders, when we do not want to compromise our faith positions? I suggest we must learn to compromise our public policies. We do it for other deeply felt issues. We did not agree when life ended, but when heart transplants became a possibility, Harvard convened a committee to set criteria for brain death, an imperfect, but usable, compromise that allowed transplant research to develop. The U.S. now leads the world in successful transplant surgical techniques. We still do not agree, but we publicly fund this research, allowing each family and physician to make private choices.

In the last 6 months, I have traveled to three countries to look at their stem cell research and meet with their scientists—in Israel, in England, and Korea. In each of these places, I also met with the bioethicists and philosophers, who demanded careful, national, and public oversight. What I saw was impressive. These

countries understood that turning their full attention to science is not only prudent in our global society, it is compassionate, it is the right thing to do to shape your country's future toward healing.

Ought we to tremble when we cross such a threshold of human knowledge? Of course. For we are being asked to understand things that were impossible to know a decade ago. Of course, we need to think soberly about the possibility that research may still fail utterly or lead us into dangerous places. That is the very nature of free research. Courage to face the problem will mean a compromise that can be regulated.

I would urge a far broader policy than our American scientists face now, for it is too late to ban the basic science of human embryonic stem cells. Where that road may turn us to is unknown, but what is certainly known is that if we, as Americans, turn aside, we will watch others pass us by. Our challenge will be how to live bravely and decently in a complex world of difficult moral choices.

I tell my son that he must write about the core question of ethics, "What must I do about the suffering of the other person?" Stem cell science reminds us that we are most human when we act as healers. We are the most free when we can explore what we don't yet know. And we are bound by a duty to shape our work, always to care for the person in need.

Thank you.

[The prepared statement of Dr. Zoloth follows:]

PREPARED STATEMENT OF LAURIE ZOLOTH, PH.D, PROFESSOR, BIOETHICS AND RELIGION, MEDICAL HUMANITIES AND BIOETHICS PROGRAM AND DIRECTOR OF BIOETHICS, CENTER FOR GENETIC MEDICINE, FEINBERG SCHOOL OF MEDICINE, NORTHWESTERN UNIVERSITY

The Ethical Issues in Human Embryonic Stem Cell Research

Mr. Chairman, Senators:

My name is Laurie Zoloth, and I am a professor of bioethics and religion in the Medical Humanities and Bioethics program, and director of bioethics at the Center for Genetic Medicine at the Feinberg School of Medicine, Northwestern University in Illinois. I want to thank the Committee for asking us to testify about the ethical issues in human embryonic cell research, and tell you why my University and many of the organizations in which I serve—the Howard Hughes Medical Institute, the International Society for Stem Cell Research, the AAAS, the NAS, support and encourage human embryonic stem cell research. First, for it is part of our broad commitment to the translation of basic medical research into the great moral enterprise of healing—serving the public's health is the core moral gesture of the medicine we teach. Second, we support stem cell research as a free academic activity, like free speech, that must be protected and sustained in our University and that must be both funded and regulated in full view of the public.

As I wrote this speech, my 10th grader was also writing a speech about stem cells—I note this not tangentially, nor merely to remind that I am a mother of five, and I, like each of you, worry about the sort of moral universe I will leave to my children, but to stress how central this debate has become in our American democracy—it is the subject of how we speak of healing and our duty to heal, and it is the subject when we speak of human dignity, and it is how we express our hope and our fear of the future. Stem cells are important in this way because of the serious rumor of hope they carry for millions of yearning patients and families. As an early watcher of the science of stem cells, I have listened carefully to the excitement of the researchers, and while ethicists urge caution and avoid hyperbolic claims, most ethicists are convinced that the sincerity and veracity of a growing body of evidence about how these cells can be coaxed into useful tissue, and how these cells can explain the very nature of how cells grow, change and divide and die—in short, how disease plays out at the cellular level—is stunningly important. If even some of what we are told to hope for is correct, then how we think about illness and injury will be transformed.

So why do ethical considerations stop full funding of this science? I would argue that there are three issues: where we get the cell, how we get the cell and what we use them for. First, is the issue of the origins of the cells, which means the moral status of the human blastocyst—can we destroy blastocysts, made in the lab, for any purpose? Can we do it for medical research and why or why not? Second is the process that researchers need to get eggs and sperm donated fairly and safely and responsibly, and handled with dignity. How are women's special needs protected? How do we protect human subjects in the first stages of this research? Finally, if researchers can find successful therapies, how will good goals of medicine be protected, and access to the therapies be fair? Can we come to agreement on the proper ends of medicine?

Stem cells are interesting to ethicists for precisely the same reason that they are intriguing to the market—they represent a therapeutic intervention that, unlike heart transplants, could be universally available, replicable and scaleable. If the daunting problems of histocompatibility can be overcome, embryonic stem cells could be made universally acceptable to anybody. Unlike adult stem cells, which would have to be created each time for each particular user, the premise of application is the wide use. Bioethicists defend high intensity interventions like organ transplant, which have saved, albeit at high cost, thousands of individuals. But organ transplants are terribly expensive, and always rationed, and the risks considerable. Stem cell research is aimed at a wider community of vulnerable patients, and at no one particular category, age, ethnicity, or class. The sort of injury and diseases that stem cells are indicated for are not boutique, or rare—cell death and cell growth is at the core of nearly all disorders. Research into these essential causes would be precisely the sort of research we ought to insist on. Further, understanding how embryonic cells are programmed and reprogrammed might allow us to understand how to de-program cells, allowing adult cells to regenerate, teaching the body to heal itself. The demand for justice and the scrutiny to which genetic medicine is given are indications that we understand the power of genetics to reconfigure the self, and the society—in this way, the very debate about stem cells forces precisely the justice considerations that I would argue must be a part of medicine. The principle of justice places a priority on the public aspects of research—on public funding and on public oversight review boards for protocols.

I think we can come to some agreement—around the duties of just medicine, and just science, and we have in the past come to agree on the how we must treat human research subjects and regulate that process, but I think we cannot come to some sort of agreement on what most divides us today—when human life begins, for this is a profoundly religious question in a profoundly religious country, profoundly dedicated to the proposition the our freedom to faithfully interpret our faith is the core of American life. For nearly all Jews, most Muslims, many Buddhists, and many Protestants, it is not only permissible to use human blastocysts to create stem cell lines, it is morally imperative—it must be done if it can lead to saving lives or healing. As an orthodox Jew, I understand the blastocyst, made in the lab, at the very first stages of division, prior to the time it could even successfully be transferred to a women's body as just what it is at that moment: a cluster of primitive cells. It does not have the moral status of a human child—it lacks a mother's womb, it existence is only theoretical without this, and even in the course of a normal pregnancy a blastocyst at 3 days is far before our tradition considers it a human person. While I respect that this is a difference in theology, and while I understand the passion and the conviction of those for whom the blastocyst is a person from the moment of fertilization, I do not believe this, and it is matter of faith for me as well. My passion and my conviction are toward the suffering of the one I see in need, ill, or wounded—for Jews and Muslims, the commandment to attend to this suffering is core to our faiths. Jewish organizations from Hadassah to the rabbinic and lay boards of all national Jewish denominations speak in one voice on this matter: human embryonic stem cell research is an activity of *pikuach nefesh,* saving and healing broken lives, and of *tikkun olam*—repairing an unfinished natural world.

What are you to do, as leaders of our polity when we will not compromise faith positions? I suggest we must learn to compromise our faith policies—we do for other deeply felt issues and we must in this case as well. For example: we did not agree when life ended, but when heart transplants became a possibility, Harvard convened a committee to set criteria for "brain death"—an imperfect, biologically ragged, but useable compromise that allowed transplant research to develop. The U.S. leads the world in successful transplant surgical techniques—and yet some faiths do not agree on these criteria. We do not agree on prenatal diagnosis, yet this is widely done, as is IVF even if it means embryos are destroyed to get one successful pregnancy. We do not agree, but we publicly fund and publicly go forward with research about these polices and we allow each family and physician to make private

choices. We do this by a combination of courage and compromise—you shape our policy in different ways: Republicans in one way, Democrats in another, but both allow for research to go forward with limits, based in time, or geography. Now it is time to revisit these limits.

In the last six month, I have traveled to three countries to look at their stem cell research and meet with their scientists: Israel, England and Korea. In each of these places, I also met with the bioethicists, philosophers, legal scholars and theologians who reflect on the research—who have demanded the same sort of careful, national, and public oversight I would think ethically important. What I saw was impressive—and for this committee in particular, critical. I saw that these countries understood that basic research in biology would be a core driver of their economy, that the knowledge, wisdom and energy that inspired that research would open the door to a world of new possibilities, some false starts, to be sure, but perhaps-just perhaps—some new starts. These countries understand that turning their full attention to science is not only prudent in our competitive global world, it is compassionate—it is the right thing to do to shape your country's future toward healing the needs of the suffering. In South Korea's labs, they meet at dawn to begin the work every single day, working with the same passion and government support we give to our Mars Rover programs, for example.

Ought we to tremble when we cross such a threshold of human knowledge? Ought we to worry that we may be going too far or too fast? *Of course,* for we are being asked to understand the world differently, the self differently, what it means to be human and to be unique, differently—to know and to see things which were impossible to know or see a decade ago. *Of course* we need to think soberly about the possibility that the research may fail utterly, or that it may succeed but lead us into a place of great unpredictability—that is the very nature of research—that is why the future is what makes us free, this uncertainty.

Courage to face the problem will mean a compromise that can be regulated, as we did with recombinant DNA, as we did in organ transplantation. I would urge a far broader and more open policy than our American scientist face now, for it is far too late to stop, ban, or have a moratorium on the basic science of human embryonic stem cells—it not only will proceed, it has proceeded, in Asia, Israel, Europe and England. Stem cell research will now clearly be a possible road. Where that road might turn us is unknown—but what is certain is that if we turn off the road, we will watch others pass us by. Our challenge-and this means each of us—scientist, citizen, congregant, critics and enthusiast—most of all Senator—will be how to live bravely and decently and fairly in a complex world of difficult moral choices. Can stem cell research yield therapies that could help millions who now suffer? Will it yield cures for diabetes, Parkinson's, spinal cord injury? Who can yet know? If it were able to help even some, that might be light enough in the storm filled world. I tell my son that he must raise these questions, the core questions of ethics and of biology—How are we human? How will we be free? What must I do about the suffering of the other person? And that stem cell science can remind us that we are most human when we act as healers, we are the most free when we explore what we don't yet know, and we are bound to a duty to shape our work to care always for the person in need.

Thank you.

Senator BROWNBACK. Thank you very much, Dr. Zoloth.

Mr. Doerflinger?

STATEMENT OF RICHARD M. DOERFLINGER, DEPUTY DIRECTOR, SECRETARIAT FOR PRO-LIFE ACTIVITIES, U.S. CONFERENCE OF CATHOLIC BISHOPS

Mr. DOERFLINGER. Thank you, Mr. Chairman.

Our longer written statement has been submitted for the record. I would like to review three points.

First, the need for ethical safeguards in human research. The ethical issue raised by this research arises whenever proponents of unlimited research freedom complain that ethical restraints get in the way of "progress." The Nuremberg Code and other declarations have affirmed that human life and dignity must not be trampled on in the pursuit of medical knowledge useful to others. Yet American scientists, and others dazzled by visions of technical progress,

are tempted to endorse a utilitarian ethic, and to treat helpless or unpopular members of the human race as mere means to their ends. When society has dropped its guard and failed to set clear limits, we ended up with the Tuskegee syphilis experiment, the infamous study at Willowbrook Children's Home in New Jersey, our government's Cold War radiation experiments, and other even more recent scandals. This same utilitarian approach drives those who pursue harmful experiments on human embryos today.

Because scientists and the for-profit companies that increasingly support and use their research are tempted to mistreat helpless members of the human family, society, including government, must supply the urgently needed barrier against the inhuman use of human beings.

Second, the moral status of the human embryo. Some with a vested interest in embryo research claim, and have testified before Senate committees, that the early human embryo is more like a goldfish than a human being, or at least has that moral status. But that's based on scientific ignorance. The continuity of human development and the reality of the embryo as a living organism of the human species, has actually been underscored by recent biological discoveries. The embryo is also recognized and respected as a member of the human family in numerous areas of Federal law.

Catholic moral teaching holds that human life has intrinsic dignity, not only a relative or instrumental value. Thus, every living member of the human species, including the embryo, must be treated with the respect due to a human person. To reject that position is to risk undermining the inherent and inalienable rights of human beings after birth as well, to turn these into mere privileges gained or lost depending on one's mental and physical abilities.

But even those who do not hold the human embryo to be a full-fledged human person can find embryonic stem cell research unethical. Setting aside debates on personhood, surely no one prefers funding research that requires destroying human life.

Four major advisory groups recommending Federal policies on human embryo research over two decades, three of them under Democratic administrations, have agreed that this research destroys human lives that deserve our respect. It's a simple biological fact. It is absurd to treat a human life solely as a source of spare parts for other people and claim that this demonstrates your respect for that life. The claim that the only embryos to be destroyed for research are those who "would have been discarded anyway" fails as a moral argument—all of us will die anyway. That gives no one the right to kill us. But that claim also misunderstands the consent process at fertility clinics. It would violate their professional code to take the embryos slated to be discarded and use them for research instead, or vice versa. They're two mutually exclusive categories of embryos.

In 1999, the National Bioethics Advisory Commission under President Clinton tried to explain what respect for the embryo might mean in the research context: "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research."

The burden of proof needed to justify destructive embryo research by NBAC's ethical standard has never been met. Scientific and practical barriers to the medical use of embryonic stem cells now loom larger than many expected. Meanwhile, non-embryonic stem cells and other alternatives have moved quickly into promising clinical trials for a wide array of conditions, including spinal cord injury, Multiple Sclerosis, Parkinson's disease, and heart damage, to name just a few.

Proponents' response to that evidence has been simply to abandon the Bioethics Commission's standard. They are losing the game, and have decided to move the goal post. What is now heard is that research using both embryonic and non-embryonic stem cells must be equally funded now to determine which source is best for various functions. But that would be justifiable only if the embryo deserves no respect at all, if it really were a goldfish and not a human being.

In short, Federal funding of embryonic stem cell research fails even the test offered by its proponents when they advised the Federal Government on this issue 5 years ago.

Third, the ethical slippery slope. The campaign for expanded Federal support for embryonic stem cell research cannot achieve its medical goals without violating even more ethical norms. Some claim the stem cells now eligible for Federal funds are inadequate in number and contaminated by the mouse feeder cells in which they are cultured. They say new cell lines, like those recently created with private funds at Harvard, must now be used.

But the cell lines already eligible for funding seem adequate for their intended task: conducting basic research on the advantages and disadvantages of these cells. Moreover, the new Harvard cell lines have the same deficiencies as those already eligible—they were grown on mouse feeder cells, as well—and have already developed serious genetic abnormalities typical of cancer cells, the researchers say, to be exact, typical of testicular cancer.

The cell lines that could be obtained by killing all the frozen embryos now available for research nationwide would still be inadequate in sheer number and genetic diversity to treat any major disease. To solve this problem, some researchers propose creating a new genetically diverse bank of cell lines by creating and killing numerous embryos solely for research, including a disproportionate number of embryos conceived by members of racial minorities who are under-represented at fertility clinics. Others have declared that mass production of new embryos by cloning will be essential.

Either way, the logical conclusion is this. Unless you are willing to commit yourself in the future to the mass production of human lives solely to exploit and destroy them, there is no point in funding research using so-called excess embryos now.

And there is yet another moral line to cross, beyond this. For the effort to get so-called therapeutic cloning to work in animals has generally succeeded only when cloned embryos are implanted in a womb, developed to later fetal stages, then aborted for their tissues. The biotechnology industry has supported bills in many states to authorize such fetus farming in humans, has helped pass such a law already in New Jersey, and now supports a ballot initia-

tive in California that could end up requiring the use of state funds to promote it.

In short, the promise of this approach is too speculative, and the cost too high. That cost includes the early human lives destroyed now and in the future, the exploitation of women for their eggs and perhaps in the future for their wombs, and the diversion of finite public resources away from research avenues that offer real reasons for hope for patients with terrible diseases. Let's agree to support avenues to medical progress that we can all live with.

Thank you.

[The prepared statement of Mr. Doerflinger follows:]

PREPARED STATEMENT OF RICHARD M. DOERFLINGER, DEPUTY DIRECTOR, SECRETARIAT FOR PRO-LIFE ACTIVITIES, U.S. CONFERENCE OF CATHOLIC BISHOPS

I am Richard M. Doerflinger, Deputy Director of the Secretariat for Pro-Life Activities at the U.S. Conference of Catholic Bishops. On behalf of the bishops' conference I want to thank this Subcommittee for asking us to present our views on the ethics of human embryonic stem cell research.

I. The Need for Ethical Safeguards in Human Research

The central ethical issue raised by this research is raised whenever proponents of unlimited research freedom complain that ethical restraints get in the way of "progress." This tension between technical advance and respect for research subjects is at least as old as modern medicine itself. As soon as Western thinkers began to see medicine as a *science* that could advance and acquire new knowledge, the temptation arose of using human beings as mere means to this end.

When Dr. Claude Bernard sounded an alarm against this temptation in the 19th century, the preferred victims were prisoners convicted of serious crimes. He insisted that the physician must not deliberately do harm to any human being simply to acquire knowledge that may help others:

> The principle of medical and surgical morality, therefore, consists in never performing on man an experiment that might be harmful to him to any extent, even though the result might be highly advantageous to science, *i.e.,* to the health of others. But performing experiments and operations exclusively from the point of view of the patient's own advantage does not prevent their turning out profitably to science.[1]

In 1865, Dr. Bernard was already making the important distinction between therapeutic and nontherapeutic experimentation. The fact that an experiment may benefit the research subject is only one moral requirement among others; but it is one thing to provide a human being with an experimental treatment whose outcome may also help in treating others in the future, and quite another thing simply to use him or her as a means, imposing significant risk of harm on him or her solely to benefit others.

In the Nuremberg Code, the United States and its allies responded to the horrors of the Nazi war crimes by restating this principle, to ensure that human dignity would not again be trampled on in the pursuit of medical knowledge. Among other things, the Code declared: "No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur . . ."[2]

This Code inspired many later declarations, including the "Declaration of Helsinki" first approved by the World Medical Association in 1964. Here the key principle is:

> In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

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[1] Claude Bernard, *An Introduction to the Study of Experimental Medicine* (1865), quoted in Stephen Post, *Inquiries in Bioethics* (Georgetown University Press 1993), at 145.

[2] See "The Nuremberg Code (1947)" (*www.cirp.org/library/ethics/nuremberg/*). The Code acknowledges one possible exception to this norm, which if taken absolutely would itself be problematic: "those experiments where the experimental physicians also serve as subjects." Researchers have a moral responsibility to take due care of their own lives as well.

The Helsinki declaration noted that this principle must apply to *all* human beings, and that "some research populations," including those who cannot give consent for themselves, "need special protection."[3] It seems this principle was intended to encompass the unborn, as the same organization's statement on the ethics of the practicing physician, the "Declaration of Geneva," had the physician swear that "I will maintain the utmost respect for *human life, from the time of conception.*"[4]

Despite these solemn declarations, American scientists and others dazzled by visions of technical progress have always been tempted to endorse a utilitarian approach to ethics, and to treat helpless or unpopular members of the human race as mere means to their ends.

In the Tuskegee syphilis experiment, for example, hundreds of poor black sharecroppers were deliberately left with untreated syphilis for over twenty years to observe the course of their disease. This was no isolated aberration but a sustained, decades-long study conducted with U.S. Government support. A report filed by the Public Health Service at the end of the process, in 1953 (years *after* Nuremberg!), shows no trace of ethical concern—rather, the authors comment favorably on how subjects were encouraged to comply with the study by the offering of "incentives"—including the offer of free burial assistance once they died from their untreated syphilis! The authors concluded: "As public health workers accumulate experience and skill in this type of study, not only should the number of such studies increase, but a maximum of information will be gained from the efforts expended."[5]

There were indeed more such studies. We need only think of the study at Willowbrook children's home, where retarded children in the 1960s were deliberately injected with hepatitis virus to study ways of preventing spread of the disease. One justification offered by the researchers was that hepatitis was so common in the institution that these children probably would have been exposed to it anyway—an argument we now see in the embryo research debate, when researchers insist that the human embryos they destroy probably would have been discarded anyway.[6] Or we can look to our government's Cold War studies on the effects of radiation using unsuspecting military *and* civilian subjects, conducted from the 1940s to the 1970s—where the drive to pursue knowledge could claim additional support from the drive for national security.[7]

The same utilitarian approach drives those who seek to justify harmful experiments on human embryos today. When asked in 1994 whether the National Institutes of Health's Human Embryo Research Panel should base its conclusions on the principle that "the end justifies the means," the Panel's chief ethicist quoted the man known as the father of situation ethics, Joseph Fletcher: "If the end doesn't justify the means, what does?"[8] This ethicist later became the chief ethicist for Advanced Cell Technology, the Massachusetts biotechnology company most prominent in the effort to clone human embryos for research purposes. Interestingly, Fletcher himself claimed that the phrase originally came from Nikolai Lenin, who reportedly used it to justify the killing of countless men, women and children in the Russian revolution of 1917.[9]

History provides us with little reason to favor utilitarian thinking about human life—for even judged by its own terms, making moral judgments solely on the basis of consequences has so often had terrible consequences. Because scientists, and the for-profit companies that increasingly support and make use of their research, are always tempted to treat helpless members of the human family as mere means to their ends, the rest of society—including government—*must* supply the urgently needed barrier against unethical exploitation of human beings.

II. The Moral Status of the Human Embryo

Some will object that one-week-old human embryos, uniquely among all classes of living human organisms, deserve no such protection from destructive experi-

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[3] World Medical Association, "Declaration of Helsinki" (*www.wma.net/e/policy/17-c__e.html*).

[4] World Medical Association, "Declaration of Geneva," reprinted in Reiser, Dyck and Curran (eds.), *Ethics in Medicine* (The MIT Press 1977), at 37. In the Declaration's 1994 revision, this phrase was amended to "human life from its beginning" (*www.wma.net/e/policy/17-a__e.html*).

[5] Eunice Rivers *et al.,* "Twenty Years of Follow-Up Experience in a Long-Range Medical Study," 68 *Public Health Reports* 391–5 (April 1953).

[6] See the source materials in J. Katz, *Experimentation with Human Beings* (New York: Russell Sage Foundation 1972) at 1007–8.

[7] See A. Skolnick, "Advisory Committee Report Recommends That U.S. Make Amends for Human Radiation Experiments," 274 *Journal of the American Medical Association* 933 (Sept. 27, 1995).

[8] Ronald Green, in Transcript of the NIH Human Embryo Research Panel (National Institutes of Health: Rockville, MD 1994), Monday, April 11, 1994, at 92.

[9] J. Fletcher, *Situation Ethics: The New Morality* (Philadelphia: Westminster Press 1966) at 120–21.

ments. They hold that these embryos, "according to science, bear as much resemblance to a human being as a goldfish." [10]

But this is simply scientific ignorance. Modern embryology textbooks tell us that the initial one-celled zygote is "the beginning of a new human being," and define the "embryo" as "the developing human during its early stages of development." [11]

The continuity of human development from the very beginning, and the reality of the early embryo as a living organism of the human species, has been underscored by recent biological discoveries. Commenting on these new findings, a major science journal concluded that "developmental biologists will no longer dismiss early mammalian embryos as featureless bundles of cells." [12] Political groups may still attempt to do so, of course, but they cannot claim that science is on their side.

While it makes no sense to say that any of us was once a body cell, or a sperm, or an egg, it makes all the sense in the world to say that each of us was once an embryo. For the embryo is the first stage of my life history, the beginning of my continuous development as a human organism. This claim makes the same kind of sense as the claim that I was once a newborn infant, although I do not have any recollection of cognitive or specifically human "experiences" during that stage of life.

The principle that the embryo deserves recognition and respect as a member of the human family is also already reflected in numerous areas of Federal law.[13] At every stage of development, the unborn child in the womb is protected by Federal homicide laws as a separate victim when there is a violent attack upon his or her mother.[14] That same child is recognized in Federal health regulations as an eligible patient deserving prenatal care.[15] And of course, for the last eight years that same embryo has been protected, in much the same way as other human subjects, from being harmed or killed in federally funded research.[16]

Catholic moral teaching on this issue is very clear. Every human life, from the first moment of existence until natural death, deserves our respect and protection. Human life has *intrinsic* dignity, not only a relative or instrumental value; thus every living member of the human species, including the human embryo, must be treated with the respect due to a human person.[17] We hold further that attempts to make a principled argument as to why embryos need *not* be respected as persons end up excluding many other members of the human race from this status as well. Any mental or physical ability or characteristic (aside from simple membership in the human race) that one may propose as the deciding factor for "personhood" will be lacking in some people, or held more by some people than by others.[18]

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[10] Mary Tyler Moore, Testimony on behalf of the Juvenile Diabetes Foundation before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education, September 14, 2000.

[11] K. Moore and T.V.N. Persaud, *The Developing Human: Clinically Oriented Embryology,* 7th edition (Saunders: Philadelphia 2003), at 2, 3. For similar statements from other textbooks see USCCB Secretariat for Pro-Life Activities, "What is an Embryo?", at *www.usccb.org/prolife/issues/bioethic/fact298.htm*.

[12] H. Pearson, "Your destiny, from day one," 418 *Nature* 14–15 (4 July 2002) at 15. For an overview of the recent findings see the Appendix to our June 2003 testimony to the President's Council on Bioethics, reprinted as R.M. Doerflinger, "Testimony on Embryo Research and Related Issues," 3 *National Catholic Bioethics Quarterly* 767–86 (Winter 2003) at 783–6.

[13] This is even generally true in the context of abortion, wherever Supreme Court decisions have allowed the legislative branch to make policy choices (as with Federal funding of abortion). In any event, the Supreme Court has allowed legislatures to respect unborn human beings and recognize them as human persons, in contexts other than abortion. *Webster* v. *Reproductive Health Services,* 492 U.S. 490, 506–07 (1989). Because the human embryo in the laboratory is not encompassed by any reproductive liberty or "privacy" defined in the Court's abortion decisions, there is no constitutional barrier to the laws passed by several states against destroying embryos in the laboratory. The research that some members of Congress want to subsidize with Federal funds would be a felony in their own home states. See USCCB Secretariat for Pro-Life Activities, "Current State Laws Against Human Embryo Research," *www.usccb.org/prolife/issues/bioethic/states701.htm,* and "Current State Laws on Human Cloning," *www.usccb.org/prolife/issues/bioethic/statelaw.htm*.

[14] Laci and Conner's Law, signed into law April 1, 2004 (Pub. L. 108–212).

[15] Final Rule: State Children's Health Insurance Program; Eligibility for Prenatal Care and Other Health Services for Unborn Children, 67 *Fed. Reg.* 61956–74 (Oct. 2, 2002) at 61974 (definition of "child" includes "the period from conception to birth").

[16] The version currently in effect is Section 510 of Division E of the Consolidated Appropriations Act of 2004 (Pub. L. 108–199).

[17] See Pope John Paul II, *Evangelium vitae (The Gospel of Life)* (1995), nos. 60–63.

[18] Thus human life must be respected as having intrinsic dignity before birth, or it will not have such dignity even after birth. This is recognized by many ethicists favoring human embryo research, most famously by Peter Singer of Princeton University. Ronald Green, cited above for his role in the embryo research debate, holds that there is nothing objective in *any* human being that demands our recognition of that human as a "person"—rather, society may judge in given

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Thus Catholic morality regarding respect for human life, and any secular ethic in agreement with its basic premises, rejects all deliberate involvement with the direct killing of human embryos for research or any other purpose. Such killing is gravely and intrinsically wrong, and no promised beneficial consequences can lessen that wrong. This conviction is also held by many American taxpayers, who should not be forced by government to promote with their tax dollars what they recognize as a direct killing of innocent human persons.

But even those who do not hold the human embryo to be a full-fledged human person can conclude that embryonic stem cell research is unethical. Many moral wrongs fall short of the full gravity of homicide but are nonetheless seriously wrong. Setting aside "personhood," surely no one prefers funding research that requires destroying human life.

Four major advisory groups recommending Federal policies on human embryo research over the past 23 years have agreed that the destruction of human life is exactly what is at stake in research that involves destroying human embryos. For example, the Ethics Advisory Board to the Department of Health, Education and Welfare concluded in 1979 that the early human embryo deserves "profound respect" as a form of developing human life (though not necessarily "the full legal and moral rights attributed to persons").[19] The NIH Human Embryo Research Panel agreed in 1994 that "the preimplantation human embryo warrants serious moral consideration as a developing form of human life."[20] In 1999, the National Bioethics Advisory Commission (NBAC) cited broad agreement in our society that "human embryos deserve respect as a form of human life."[21] And in 2002, the National Academy of Sciences acknowledged that "in medical terms," the embryo is a "developing human from fertilization" onwards.[22]

What does this respect mean, if it does not mean full and active protection from harm of the kind we extend to human persons? At a minimum, doesn't it mean that we will not use public funds to promote such harm? It is absurd to treat a human life solely as a source of spare parts for other people, and claim that this demonstrates your "respect" for that life. It is equally absurd to fund stem cell research that encourages researchers to destroy human embryos for their cells, and claim that one is not promoting disrespect for the lives of those embryos.[23]

It does not help this argument to claim that the only embryos to be destroyed for research are those who "would have been discarded anyway." The mere fact that some parents discard "excess" embryos creates no argument that the Federal government should intervene to assist in their destruction—any more than the fact that many abortions are performed in the U.S. creates an argument that Congress must use its funding power to promote such killing. In fact, Congress has for many years *rejected* arguments that it can fund harmful experiments on unborn children slated for abortion because "they will die soon anyway." See 42 U.S.C. § 289g. The claim that humans who may soon die automatically become fodder for lethal experiments also has ominous implications for condemned prisoners and terminally ill patients. In the final analysis, all of us will die anyway, but that gives no one a right to kill us.

Even on its own amoral terms, that argument also misunderstands the informed consent process for "disposition" of frozen embryos in U.S. fertility clinics. When these clinics produce more embryos in a given cycle than parents need for their immediate reproductive goals, they do indeed freeze the "excess" embryos and ask the parents what should be done with them after a given time. Most clinics offer the options of continuing to preserve the embryos, using them for further reproductive

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cases that born humans, as well, have qualities making them more valuable dead than alive. Ronald M. Green, "Toward a Copernican Revolution In Our Thinking About Life's Beginning and Life's End," 66 *Soundings* 152 (1983) at 159–160. If one attempts to develop and apply objective criteria for personhood, based for example on cognitive abilities, says Green, then "it seems to be true that if the fetus is not a person, neither is the newborn or young infant." *Id.* at 156.

[19] "Report of the Ethics Advisory Board," 44 *Fed. Reg.* 35033–58 (June 18, 1979) at 35056.

[20] National Institutes of Health (NIH), *Report of the Human Embryo Research Panel* (September 1994), at 2.

[21] National Bioethics Advisory Commission (NBAC), *Ethical Issues in Human Stem Cell Research* (Rockville, Maryland: September 1999), Vol. I at ii; cf. 2.

[22] National Academy of Sciences (NAS), *Scientific and Medical Aspects of Human Reproductive Cloning* (National Academy Press 2002), 262.

[23] Says ethicist Glenn McGee, who supports embryo research: "Pretending that the scientists who do stem cell research are in no way complicit in the destruction of embryos is just wrong, a smoke and mirrors game on the part of the NIH. It would be much better to take the issue on directly by making the argument that destroying embryos in this way is morally justified—is, in effect, a just sacrifice to make." Quoted in J. Spanogle, "Transforming Life," *The Baylor Line* (Winter 2000) at 30.

efforts by the couple, donating them to another couple for reproduction, discarding them, or donating them for research. But these are *mutually exclusive options.* For example, it would violate the professional code of the fertility industry to take embryos "to be discarded" and use them for research instead. And among embryos donated for research, no researcher or government official can tell which embryos "would have been discarded" if this option had not been offered.[24]

The problem with past Federal advisory panels is that they have generally failed to give any real content to the notion of "respect" or "serious moral consideration" for the embryonic human. The NIH Human Embryo Research Panel failed miserably in this task. Since the Panel approved a wide array of lethal experiments on human embryos—including some which required specially creating embryos solely to destroy them—even the Panel's own members publicly observed that it had come to use the word "respect" merely as a "slogan" with no moral force.[25]

In the end, the Panel's report was rejected in part by President Clinton (who denied funding for experiments involving the creation of embryos for research), and rejected in its entirety by Congress (which enacted the appropriations rider against funding harmful embryo research that remains in law to this day).

Five years later, the National Bioethics Advisory Commission tried to give more definition to what "respect" for the embryo might mean in the research context:

> *In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research.*[26]

While this standard does not fully respect the embryo as a person with inviolable rights, it creates a presumption against research that requires killing embryos: Such research was to be a last resort, pursued *only* after it is found that research benefits cannot be pursued in any other way. However, the Commission then evaded the implications of this standard, by ignoring the emerging evidence about the promise of adult stem cells and other alternatives. But the Commission admitted that its factual claim on this point must be reevaluated as scientific knowledge advanced.

As the National Institutes of Health acknowledged in 2001, the burden of proof needed to justify human embryo research by NBAC's ethical standard has never been met. The NIH's review of stem cell research concluded that any therapies based on embryonic stem cells were "hypothetical and highly experimental," and that it could not be determined at that time whether these cells would have *any* advantages over the less morally problematic alternatives.[27]

Since that time, in fact, scientific and practical barriers to the medical use of embryonic stem cells have loomed larger than many scientists expected in 1999. Problems of tumor formation, uncontrollability, and genetic instability are now cited among the reasons why embryonic stem cells cannot safely be used in human trials any time in the foreseeable future.[28] At the same time, non-embryonic stem cells have moved quickly into promising clinical trials for a wide array of conditions, including spinal cord injury, multiple sclerosis, Parkinson's disease, heart damage and corneal damage.[29]

Many researchers and biotechnology companies have responded to this evidence by simply abandoning NBAC's standard. In short, they are losing the game and have decided to move the goalpost.

What is now often heard is that research using both embryonic and non-embryonic stem cells must be fully funded now, to determine which source is best for various functions. In other words, we must help researchers violate NBAC's ethical

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[24] In its 1999 report, NBAC recommended that clinics first offer parents the option of having their embryonic children destroyed, and only then offer a choice between discarding and destructive research as the two ways of destroying them. NBAC, note 21 supra at 53. Such a policy *might* provide a factual basis for determining that embryos slated for research would have been destroyed anyway. But as far as anyone can determine, no fertility clinic has taken this approach. The number of frozen embryos in the United States now designated for research, that one can determine would only have been "discarded anyway," is zero.

[25] Transcript, note 8 *supra,* April 11, 1994, at 40 (remarks by Dr. Bernard Lo).

[26] NBAC, note 21 *supra,* at 53.

[27] NIH, *Stem Cells: Scientific Progress and Future Research Directions* (Dept. of Health and Human Services, June 2001), at 17; also see 63 (any possible advantages of embryonic cells remain to be determined), 102 (not known whether these cells are better suited for gene therapy).

[28] See the sources cited in USCCB Secretariat for Pro-Life Activities, "Practical Problems with Embryonic Stem Cells," *www.usccb.org/prolife/issues/bioethic/stemcell/obstacles51004.htm*.

[29] See: the sources cited in USCCB Secretariat for Pro-Life Activities, "Scientific Experts Agree: Embryonic Stem Cells are Unnecessary for Medical Progress," *www.usccb.org/prolife/issues/bioethic/fact401.htm;* Testimony of Susan Fajt, Laura Dominguez, and Dennis Turner before this Subcommittee, July 14, 2004, at *www.stemcellresearch.org/testimony/index.html;* and the constantly updated reports of therapeutic advances at *www.stemcellresearch.org*.

standard now, to determine whether they will ever be able to meet the burden of proof that standard places on them.

But this approach simply reduces "respect" for the embryo to nothing at all. For that is the approach one would take if there were no moral problem whatever—if the only factor determining our research priorities were relative efficiency at achieving certain goals. "Respect" must mean, at a minimum, that we are willing to give up some ease and efficiency in order to obey important moral norms instead of transgressing them.

At this point, it is not even established that continued pursuit of embryonic stem cell research would increase the ease and efficiency of arriving at any treatments, for it may only divert attention and resources away from alternative approaches that could cure diseases more quickly.

In short, using Federal funds to encourage the destruction of embryos for new stem cell lines not only fails the test of a principled "sanctity of life" ethic. Given the lack of clear evidence for any unique or irreplaceable role for embryonic stem cells in the treatment of devastating diseases, it even fails the test offered by *proponents* of human embryo research when they advised the Federal government on this issue five years ago.

III. The Reality of an Ethical Slippery Slope

The campaign for expanded Federal support for embryonic stem cell research also ignores the fact that its goal cannot be achieved without violating even more ethical norms. Any agenda that will inevitably require such further violations in order to produce any of its promised results must be held accountable now for justifying those violations. Otherwise our government could waste years of effort and millions of dollars on an approach that must be abandoned in midstream, before producing results—with devastating consequences for patients now awaiting treatments.

At present, contrary to many misleading comments in the political debate, there are no set limits on the amount of Federal funding that may be allocated for embryonic stem cell research. However, current policy is to fund only research using the embryonic stem cells obtained by destroying human embryos prior to August 9, 2001. These cell lines are intended to be adequate only for basic research, to determine whether embryonic stem cells offer uniquely promising benefits without encouraging the destruction of live embryos to obtain the cells for that project.

Some claim the currently eligible cell lines are inadequate in number and "contaminated" by the mouse feeder cells used to culture them. They argue that new cell lines like those recently created with private funds by Harvard researchers, and the "more than 400,000 IVF embryos" now frozen that could be used for research, must not be allowed to go to waste. The implied argument is that if only these additional cell lines, and currently existing "excess" embryos, were offered up for federally funded research, researchers would have all they need to cure terrible diseases.

But even if embryonic stem cells could ever be used to cure serious illnesses—which at this point is hypothetical—this argument makes no sense. It is important to understand why.

First, it has not been shown that the cell lines already eligible for funding are inadequate for their intended task—conducting basic research in the advantages and disadvantages of these cells. Because some of the cells were frozen for later use immediately after being harvested from embryos, the number of actual cell lines continues to grow as the cells are thawed and cultured. For example, there were 15 lines when House members wrote to President Bush urging an expanded policy this summer, and 19 by the time the Senate letter was circulated a few weeks later. According to the NIH, over 400 derivatives of these lines have been shipped to researchers as of February 2004. Some cells remain frozen at this point (and so could be cultured without the "contamination" of animal feeder cells if necessary), while over two dozen eligible cell lines are currently unavailable to federally funded researchers only because their owners have not yet agreed to share them with other researchers.[30]

Second, the new Harvard cell lines have the same deficiencies as the currently eligible cell lines. They are inadequate for any significant clinical use, they were cultured in mouse feeder cells, and—most interesting of all—they have already developed serious genetic "abnormalities" in culture.[31] A recent study suggests that *all*

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[30] See A. Robeznieks, "The politics of progress: How to continue stem cell research despite limitations," *American Medical News,* August 9, 2004, *www.ama-assn.org/amednews/2004/08/09/prsa0809.htm#s1.*

[31] The abnormal cells have a "proliferative advantage" over the remaining normal cells in the culture, suggesting that these cell lines may soon consist largely of abnormal cells. C. Cowan *et al.,* "Derivation of Embryonic Stem Cell Lines from Human Blastocysts," 350(13) *New England Journal of Medicine* 1353–6 (March 25, 2004) at 1355.

human ESC lines may spontaneously accumulate extra chromosomes that are typical of human embryonal carcinoma cells from testicular cancer.[32]

Third, the Rand study which concluded that there may be as many as 400,000 frozen embryos in the United States also found that only 11,000 (less than 3 percent of the total) are designated by parents for possible use in research. If *all* these 11,000 frozen embryos were destroyed for their stem cells (seen by the authors as a "highly unlikely"scenario), this may produce a grand total of 275 cell lines—surely inadequate for use in treating any major disease.[33]

Last year an opinion piece attacking President Bush's policy cited two prominent researchers in support of the claim that merely determining the "best options for research" (to say nothing of clinical use) would require "perhaps 1,000" stem cell lines—about four times as many as those which could be obtained by destroying every available human embryo in frozen storage nationwide.[34] Another group of researchers has concluded that in order to reflect the genetic and ethnic diversity of the American population, an embryonic stem cell bank geared toward treating any major disease would have to include cell lines from many embryos created solely in order to be destroyed for those cells—including a disproportionate number of specially created embryos conceived by black couples and other racial minorities, who are underrepresented among current fertility clinic clients.[35] Yet another prominent stem cell researcher estimated that unless researchers resort to human cloning to produce genetically matched stem cells for each patient, "millions" of embryos from fertility clinics may be needed to create cell lines of sufficient genetic diversity for clinical use.[36]

Of course, trying to address this problem with cloning would require specially creating and then destroying many millions of embryos as well—an estimated hundred embryos per individual patient, potentially requiring the exploitation of many millions of women for their eggs to treat even one major disease.[37] Undaunted, the national Biotechnology Industry Organization (BIO), in a statement echoed by many researchers, has testified that the use in humans of the cloning technique that created Dolly the sheep will be "essential" to realizing the promise of embryonic stem cell research.[38]

BIO's testimony on this point should help to clarify our minds, for it may be rephrased as follows: Unless you are willing to commit yourself in the future to human cloning and the mass-production of human lives in order to exploit and destroy them, there is no point in promoting federally funded research using so-called "excess" embryos now.

And there is yet another moral line to cross beyond this. For the effort to use human embryo cloning for "therapeutic" purposes involves all the practical barriers inherent in embryonic stem cell research in general, plus some additional problems. For example, even cloned embryos with a normal genetic makeup generally suffer from chaotic gene expression, leading to many embryonic and fetal deaths and to increased risks in using any cells from these embryos for future therapies. There

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[32] J. Draper *et al.,* "Recurrent gain of chromosomes 17q and 12 in cultured human embryonic stem cells," 22 *Nature Biotechnology* 53–4 (2003).

[33] D. Hoffman *et al.,* "Cryopreserved embryos in the United States and their availability for research," in 79 *Fertility and Sterility* 1063–9 (2003) at 1068.

[34] S. Hall, "Bush's Political Science," in *The New York Times,* June 12, 2003, A33.

[35] R. Faden *et al.,* "Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy," in *Hastings Center Report,* November–December 2003, 13–27.

[36] R. Lanza and N. Rosenthal, "The Stem Cell Challenge*," Scientific American* (May 2004), 93–99 at 94. Another study, while noting that other solutions to the immune rejection problem might be found, agrees that the creation of a sufficiently diverse bank of embryonic stem cell lines is "almost impossible." M. Drukker and N. Benvenisty, "The immunogenicity of human embryonic stem-derived cells," 22(3) *TRENDS in Biotechnology* 136–141 (March 2004) at 138.

[37] "Optimistically, ~100 human oocytes would be required to generate customized ntES cell [nuclear transfer embryonic stem cell] lines for a single individual . . . human oocytes must be harvested from superovulated volunteers, who are reimbursed for their participation. Add to this the complexity of the clinical procedure, and the cost of a human oocyte is ~$1,000–2,000 in the U.S. Thus, to generate a set of customized ntES cell lines for an individual, the budget for the human oocyte material alone would be—$100,000–200,000. This is a prohibitively high sum that will impede the widespread application of this technology in its present form." P. Mombaerts, "Therapeutic cloning in the mouse," 100 *Proceedings of the National Academy of Sciences* 11924–5 (September 30, 2003) at 11925.

[38] "Somatic cell nuclear transfer research is essential if we are to achieve our goals in regenerative medicine." Testimony of Thomas Okarma on behalf of BIO before the House Energy and Commerce Subcommittee on Health, June 20, 2001, *http://energycommerce.house.gov/107/hearings/06202001Hearing291/Okarma450.htm.* During the question session Dr. Okarma made it clear he meant the use of this technology to create genetically tailored human embryos for research, including stem cell research.

is evidence that there may be a later opportunity in fetal development to correct these gene expression problems, if the embryo can survive to that point.[39]

Perhaps due partly to this phenomenon, the major studies seeking to provide an animal model for "therapeutic" cloning have found it necessary to *implant the cloned embryo in a womb and develop it past the embryonic stage* to obtain usable cells and tissues.[40] Thus the old alleged distinction between "reproductive" cloning (placing cloned embryos in a womb for gestation) and "therapeutic" cloning (destroying cloned embryos for research purposes) is breaking down, as the former increasingly becomes a necessary component of the latter.

BIO has already acted to provide legislative authorization for this approach in humans—by supporting state laws to allow researchers to clone human embryos and develop them in wombs into the last stages of *fetal* development, as long as they do not allow a full-term *live birth.*[41] One such law has already been enacted, in New Jersey.[42] And the pending California ballot initiative known as Proposition 71, which would force the financially strapped state government to borrow $3 billion to fund embryonic stem cell and human cloning research, would "initially" forbid developing cloned human embryos past 12 days—but allow indefinite expansion of this limit, by vote of a new Oversight Committee dominated by stem cell advocates.[43]

In short, no new breakthroughs have shown that embryonic stem cells are ready or almost ready for clinical use. Use of new cell lines from frozen embryos has not been shown to be necessary for current basic research, and would still be completely inadequate for any large-scale clinical research—suggesting that proposals for expanding the current embryonic stem cell policy are themselves only a transitional step toward mass-producing embryos (by cloning or other means) solely for harmful experimentation. The for-profit biotechnology industry has known this for years, and has begun paving the legislative road toward large-scale human cloning and "fetus farming" in case these prove necessary for technical progress in this field.

Conclusion

Since human embryonic stem cells were isolated and cultured in 1998, initial hyped promises of miracle cures for devastating diseases have collided with reality. More than two decades of research using mouse embryonic stem cells have produced no treatments in mice that are safe or effective enough for anyone to propose in humans. These cells have not helped a single human being, and the practical barriers to their safe and effective use loom larger than ever. Meanwhile, alternative approaches that harm no human being have moved forward to offer realistic hope for

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[39] J. Fulka *et al.,* "Do cloned mammals skip a reprogramming step?", 22(1) *Nature Biotechnology* 25–6 (January 2004).

[40] In the first study, mice derived from cloning had to be brought to *live birth* to harvest their *adult* bone marrow stem cells. W. Rideout III *et al.,* "Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy," 109 *Cell* (April 5, 2002), 17–27. For a critique see Americans to Ban Cloning, "Why the 'Successful' Mouse 'Therapeutic' Cloning Really Didn't Work," *www.cloninginformation.org/info/unsuccessful__mouse__therapy.htm.* A second study required placing cloned cow embryos in wombs to develop them to the fetal stage, then aborting them for their kidney tissue. R. Lanza *et al.,* "Generation of histocompatible tissues using nuclear transplantation," 20(7) *Nature Biotechnology* 689–696 (July 2002). The authors wrote: "Because the cloned cells were derived from early-stage fetuses, this approach is not an example of therapeutic cloning and would not be undertaken in humans." *Id.* at 689. But these same authors published a new study this year, in which cloned mouse embryos had to be developed to 11 to 13 days of gestation (the equivalent of the fifth to sixth *month* in humans) and then aborted to obtain usable cardiac cells. R. Lanza *et al.,* "Regeneration of the Infarcted Heart With Stem Cells Derived by Nuclear Transplantation," 94 *Circulation Research* 820–7 (April 2, 2004). This time there were no disclaimers. Instead the lead author declared that this is "an important new paradigm" for human "therapeutic cloning." See Advanced Cell Technology, "Cloned Stem Cells Regenerate Heart Muscle Following a Heart Attack," February 10, 2004, *http://salesandmarketingnetwork.com/news__release.php?ID=14109&key=Advanced%20Cell%20Technology*.

[41] See Americans to Ban Cloning, "Report: State Bills on Human Cloning," March 26, 2003, *www.cloninginformation.org/info/ABC-State-Laws.htm*.

[42] See: W. Smith, "Cloning in New Jersey," in *The Daily Standard* (online service of *The Weekly Standard*), December 11, 2003, *www.weeklystandard.com/Content/Public/Articles/000/000/003/482iusla.asp;* News Article, "A safe haven for human cloning?", *The Monitor* (Newspaper of the Diocese of Trenton, NJ), December 19, 2003, *http://www.dioceseoftrenton.org/department/news__detail.asp?newsid=850*.

[43] See "California Stem Cell Research and Cures Act," Website of the Attorney General of California, *http://www.caag.state.ca.us/initiatives/pdf/sa2003rf0055amdt1__ns.pdf.* The "initial" time limit on the age of embryos to be destroyed for their stem cells (8 to 12 days) can be changed by the Oversight Committee (*Id.* at 11), whose chairperson must have a "documented history in successful stem cell research advocacy" (*Id.* at 6). The initiative places a "high priority" on stem cell research *not* eligible for Federal funding, ensuring that the funds will be used primarily for embryonic stem cell and human cloning research (*Id.* at 16).

patients who many said could be helped only by research that destroys human embryos. Campaigns for increased public funding have grown in inverse proportion to the dwindling hopes of medical benefit, as private funding sources increasingly realize that embryonic stem cell research may not be a wise investment.

We should not succumb to this latest campaign, but reflect on the ethical errors that brought us this far. Even proponents of the research have admitted that it poses an ethical problem, because it involves destroying human lives deserving our respect. Based in part on the actions and statements of proponents, we can see that still further ethical breaches will be required of Congress and society to realize the "promise" of this approach. Already the policy debate has moved from "spare" embryos in fertility clinics, to specially creating embryos for destruction, to mass production of embryos through cloning, to the gestation of these embryos for "fetus farming" and the harvesting of body parts.

Congress should take stock now and realize that the promise of this approach is too speculative, and the cost too high. That cost includes the early human lives destroyed now and in the future, the required exploitation of women for their eggs and perhaps for their wombs, and the diversion of finite public resources away from research avenues that offer real reasons for hope for patients with terrible diseases. Let's agree to support avenues to medical progress that we can all live with.

Senator BROWNBACK. Thank you very much.

That was excellent testimony presented by both of you. We have a few minutes left in this vote. We're going to go vote on this one. And there is supposed to be a second vote, and we will vote at the front end of that and then come back and consume—we'll move forward with questions on this panel.

So we will be in recess until we are able to return, hopefully in about 15 minutes.

[Recess.]

Senator BROWNBACK. I call the hearing back to order. I'm sorry it took us so long. I think we will have other Members that will be joining us. Let's run the time clock at 7 minutes so we can bounce this back and forth.

Thank you all for staying here and being with us.

Dr. Zoloth, I read your testimony last night, and I appreciate it, I appreciate the thoughtfulness of it. And I don't always get testimony read, so I wanted to make sure to look through it and to inquire of you about it. And you talk about the nature of, you know, the very ethical decision of, When does life begin? And you look at this and say, "Well, I don't think this qualifies to it." And, as I understand it, it's the issue of not being in the womb. Is that the issue of how you determine that this is not human life?

Dr. ZOLOTH. It's two different things. It's both the fact that the kind of blastocysts we're talking about are always created artificially, never inside of a woman's womb, and they're taken and used for stem cell research before the time that they would, even if they were part of a normal pregnancy cycle, be considered a human life for the legal requirements of Judaism. Because, for Jews, human life begins—and it's assessed developmentally—and the first 40 days of a pregnancy are a time of a lesser moral status, and the pregnancy really begins when it takes shape and form at the 40th day. This tradition——

Senator BROWNBACK. So it's after 40—I just want to get to——

Dr. ZOLOTH. Forty days.

Senator BROWNBACK.—this——

Dr. ZOLOTH. It's actually the tradition——

Senator BROWNBACK.—after 40 days.

Dr. ZOLOTH. After 40 days. Now, the interesting thing is, that's true not only for Jews, but for Muslims and for a long Aristotelian tradition of an unformed fetus; in fact, as our colleagues in the Catholic Church could tell us, until 1859, for many in the Catholic Church, and many who interpreted Canon law, as well. So this uncertainty about when human life begins, it's a very old, deeply understood as a religious consideration.

Senator BROWNBACK. Let me take a point, then, on that. The Democrat Presidential nominee believes life begins at conception. That's what he's stated recently. And that is at the very heart of what we're talking about here, is, when does that life begin? In your own existence, in your own case—you—when did your life begin?

Dr. ZOLOTH. That's a complicated question. My life begins in—obviously, there's an event that takes place when I, myself, comes into existence in terms of my DNA. If you're just looking at when my DNA begins to exist, obviously, at the moment of fertilization. But as a religious Jew, I believe that human life is a developmental process. You acquire moral status as you acquire more and more milestones on this developmental path. And as a religious Jew, my duties and obligations began, for me, in the classically, religiously understood terms, at the moment that I was born into the world and capable of being received as a person in my religious community. People have, then, duties to me, and I would grow in my duties to them.

Senator BROWNBACK. Well, let me ask you, biologically, when did your life begin?

Dr. ZOLOTH. Well, no one can really know that answer, because it's not a fixed biological question. Maybe it's when the first noggin gene turned on or when my cells began to organize or when the first neuron begins to assert itself.

Senator BROWNBACK. When do you believe your life began, biologically?

Dr. ZOLOTH. Biologically? I believe—I think about these things in terms of my faith's tradition and my——

Senator BROWNBACK. Biologically——

Dr. ZOLOTH.—biologically, I think my life begins as a DNA'd organism. Right? When my DNA begins to assert itself. But it's not an important——

Senator BROWNBACK. That would be the moment——

Dr. ZOLOTH.—point.

Senator BROWNBACK.—of conception, is that correct?

Dr. ZOLOTH. But that—but what moment is that, really? What moment is that? Maybe it's when I'm organized. I think that's an infinitely complex biological question, and I am—I'm not a biologist; I'm a religious Jew, so my life begins as an entity perhaps when I'm capable of living independent from my mother's body.

Now, I used to be a neonatal intensive-care nurse——

Senator BROWNBACK. Right.

Dr. ZOLOTH.—so I'm aware of how differently—before I was a philosopher—I'm aware of how differently embryos come to change and grow, and the success by which they do or don't live outside of a woman's body. And that, too, is the developmental process.

Senator BROWNBACK. Let me ask you this, then. When did the life of your son begin? You were talking about the paper he's writing. When did, biologically, his life begin?

Dr. ZOLOTH. Well, we're going to keep going back around and around that, and I think that's the question that as I'm——

Senator BROWNBACK. That's what we're trying to get at.

Dr. ZOLOTH. But I don't think it's a biological answer. For me—I don't think it's an—I don't think it's an—for me, it's not the salient point, "When does it biologically begin?" I could be convinced that—by a number of different arguments, but the most important one is that it's a biological process that doesn't have a moment of divinity or a moment of conception that is of biological importance to me. Many——

Senator BROWNBACK. OK——

Dr. ZOLOTH.—many genes have to work as a system. The system has to be successful. There are a number of different milestones before I can truly say I've biologically begun a process that will be successful.

Senator BROWNBACK. So then—but you advocate we should experiment on humans at these very early stages of development. Indeed, you would we are required to do this, justice requires this. But if we researched on me at 2 days of age, or you at 2 days biological age, or your son at 2 days biological age, would that have been appropriate?

Dr. ZOLOTH. This isn't about my son or myself, human persons at different stages within a woman's body. We're talking about blastocysts at the 3-day-age stage——

Senator BROWNBACK. OK, then——

Dr. ZOLOTH.—created outside of a womb.

Senator BROWNBACK.—blastocysts——

Dr. ZOLOTH. And I think of that—blastocysts, I would—I do believe, religiously and morally, are warranted. And, in fact, we have an imperative to research on these clusters of cells if we believe—have come to believe that they can yield cures.

Senator BROWNBACK. What would have happened had we experimented on you at the blastocyst stage?

Dr. ZOLOTH. Well, that's an obvious question. If I was—it's an odd theoretical one—if I could somehow be——

Senator BROWNBACK. It's not a theoretical. I'm just——

Dr. ZOLOTH. If I could have been taken out——

Senator BROWNBACK.—asking biologically.

Dr. ZOLOTH.—if I could have been taken out of my mother's womb, which is—which is different——

Senator BROWNBACK. What——

Dr. ZOLOTH.—from our situation, then I wouldn't have——

Senator BROWNBACK. What would have happened to you?

Dr. ZOLOTH. I wouldn't have existed, obviously. But this same token is, I'm going to be, for instance—as our colleague pointed out, I'm going to be, inevitably, dead; but I'm not now treated as though I'm dead now. I'm treated as though I'm a living philosopher, not as a dead one. And so we take account of different moments in our biological process.

Senator BROWNBACK. Do you support human cloning?

Dr. ZOLOTH. Under some limited circumstances, with a number of restraints, never for reproduction—never for reproduction—or implantation in the human womb. I do, for experimental purposes to do basic research, yes.

Senator BROWNBACK. Mr. Doerflinger, when did your life begin, biologically?

Mr. DOERFLINGER. Biologically? I think there are two different questions that we shouldn't confuse. One is a biological question. And in the embryology textbooks—there are sources cited in my testimony—say that the first one-celled embryo is "the beginning of a new human being." A simple biological fact. This is a new member, an individual member, of the species; therefore, a human being, in that sense. That's when I started, that's when everybody, as far as I know, started.

Now, the moral question, it seems to me, is what moral value we attribute to different stages of that process. Now, it's our conviction in the Catholic Church that unless you see every stage of that process as having inherent worth simply because this is a member of the human race, you end up with a theory in which nobody really has inherent rights; everybody has different moral value attributed to them based on the traits or the abilities, the mental and physical abilities, they have at any given time. You can acquire personhood, you can lose personhood when you're near the end of your life and get into a coma or have Alzheimer's, because you don't have any cognitive processes, maybe, going on then either. And we feel that's a very risky logical argument that would endanger a lot of helpless human beings.

But the Catholic Church never held that, as a matter of religion, life begins at 40 days. What we've always said is that—here's where we were doing a lot better than we did with astronomy in the Galileo case——

Dr. ZOLOTH. That's not hard.

Mr. DOERFLINGER.—we have to respect life whenever the biologists tell us it's there. And the biologists, until the 19th century, were very confused about those early stages, because they didn't know about the process of conception. They thought that the form for the new human being was entirely located in the male sperm, and they had to figure out some kind of intermediate stages for how that sperm can turn into someone who is specifically human and somehow even has traits from the mother. And in 1825, the ovum was discovered, the process of conception discovered, and, at that point, the church acknowledged that this, then, should be the beginning for moral respect, as well.

Senator BROWNBACK. Senator Wyden, I'll bet you never thought you'd get this sort of education, did you?

Senator WYDEN. That's for sure. And I'm going to ask a couple of questions to start with, for you, Dr. Doerflinger, that I'd really like just a yes or no answer to, because this is a complicated field, and it's one where sometimes the more you learn, the less you know.

And let me start by asking you about fertility clinics. I think you know that I wrote the only Federal law that's on the books now with respect to fertility clinics. It at least provides some measure of oversight and consumer protection for the millions of couples

that look to them. And my question that I'd like a yes or no answer to is, Do you support the in vitro process that is used at fertility clinics around the country?

Mr. DOERFLINGER. You mean morally?

Senator WYDEN. No, I just want to know, yes or no, do you——

Mr. DOERFLINGER. No.

Senator WYDEN.—support it. You do not.

Mr. DOERFLINGER. Right.

Senator WYDEN. If you had your way, then because of your answer millions of couples wouldn't have the opportunity to have what they want more than anything else. And your——

Mr. DOERFLINGER. No.

Senator WYDEN.—candor is appreciated on it, but——

Mr. DOERFLINGER. No, that's—no, I think that's a false statement.

Senator WYDEN. Well, how would they? I mean, that's the process that is used at fertility clinics, and you've said you don't favor——

Mr. DOERFLINGER. Well——

Senator WYDEN.—using that process.

Mr. DOERFLINGER.—that's one process that actually has a success rate that's far below a lot of other things that I have a lot less moral problem with.

Senator WYDEN. Well, that——

Mr. DOERFLINGER. I thought it was a question, so I answered.

Senator WYDEN. Well, but that—and I appreciate that. And that's what my legislation does, of course, is make it possible for people to compare success rates. But you said you don't favor a process that has provided incredible happiness to millions of couples, and you've answered my question clearly.

The reason I asked is, I wanted to lay the foundation for the second question, and that is—as you know, at fertility clinics, there are often embryos that aren't used. What do you favor being done with those embryos that are not used?

Mr. DOERFLINGER. I think I'd have to be favoring the process in order to be in the position to—obviously, I don't want them to be happening at all.

Senator WYDEN. Yes. So you're——

Mr. DOERFLINGER. I think you'd have to ask that question of someone who supports it.

Senator WYDEN. Yes, I appreciate your answer. I mean, I thought that you would be supportive of the process, and I was going to ask you some questions about whether they ought to be donated or the like. But you've answered, and I appreciate the answer.

My second question for you is, Do you think the country is better off funding embryonic stem cell research on the Federal level so that we could have one tough set of Federal ethical guidelines, rather than what I have described as this kind of crazy quilt of policy and state regulation? I think you were here when I gave my opening statement, and one of the concerns that I have is—because our citizens are so frustrated now about the inaction of the Federal Government—is, they're just, kind of, going off and doing their own thing. And so New Jersey is going to do theirs, and Harvard's going

to have a program, and California's going to have a program. And what will happen—and Senator Brownback—because he and I have sat through hours of these hearings—makes a very good case that we need a good set of ethical guidelines. This is not something I want to see done without ethical guidelines, but I think we ought to have one clear, strong set of Federal guidelines, rather than what we're going to have now, which is a sort of hodgepodge and crazy quilt. Do you think that we ought to have one set of guidelines?

Mr. DOERFLINGER. I think we have one set of Federal guidelines now, Senator.

Senator WYDEN. We do——

Mr. DOERFLINGER. Except that——

Senator WYDEN.—but that's going to change once the California ballot measure passes.

Mr. DOERFLINGER. Oh, no, I——

Senator WYDEN. It will.

Mr. DOERFLINGER. Now I understand your question.

Senator WYDEN. Yes.

Mr. DOERFLINGER. No, no, the—you could expand the Federal guidelines all you want, and there would still be a crazy quilt on what's funded by the states. Deciding that you're going to set limits or expand the limits on federally funded research doesn't change anything, one way or the other, as to privately or state-funded research. In fact, the California initiative says that it's their top priority to fund only embryonic stem cell and cloning research that is not funded by the Federal Government. So, for example, if you put these tough Federal guidelines in, and you say, "But we're only going to fund research on the spare embryos," that means all $3 billion of the California money might go into cloning. So it's not a restraint—unless you were to say, "The Federal policy is going to reach out and cover all privately and state-funded research, at all," which hasn't been done on any research, including research on adults, since the beginning of Federal regulations.

Senator WYDEN. Dr. Zoloth, do you want to answer that question, as well? Would we be better off with one standard?

Dr. ZOLOTH. Like I said, I've traveled to other countries to see how they do it, because I think it's an interesting question, and the most well-established principle is the one Britain. And, in fact, it does cover both public and private sorts of research. I believe very strongly in a Federal—reasonable Federal standard that would be—set a gold standard, as it were, for how research should be done in the Federal—in public—in publicly available labs, in privately funded labs, in pharmaceutical-company labs. I want private companies and all researchers, in fact, to have the same sort of ethical guidelines and standards so that we can publicly debate, publicly know what they're doing, and have it be a shared decision-making process, like it is with so much of other research.

Senator WYDEN. Well, I want to ask about one other area, but that's very much a view that I share, is, I think you ought to have a debate, you ought to make sure that everybody's heard. There are certainly a lot of stakeholders in this. For all practical purposes, hundreds of millions of Americans are stakeholders in this. But I think there's a reason that the states are going off and doing their

own thing. And they are not, Dr. Doerflinger, you know, pursuing human cloning and—you know, in California, they are responding to the abysmal performance of the Federal Government, in terms of restricting the lines that are available.

And I want to ask one last question on this first round, if I could, for Dr. Zoloth.

Dr. Zoloth, I think I mentioned the reports indicating that something like 21 of the initial 78 stem cell lines are now available to researchers, scientists coming forward and saying a hundred new lines have been developed since the original cutoff by the President. I mean, it seems to me that these two facts, alone—these two facts alone—show the real consequences for researchers, in terms of this "turn back the clock" approach that is being chosen by this Administration in the field. Would you like to address those two facts, alone—the question of the reduction of the number of initial stem cell lines that's actually been available, and then the new lines that have been available? Because that seems to me to be—those areas are really what's taking the toll now on the prospects for research.

Dr. ZOLOTH. I actually thought that President Bush's compromise was a sensible one when he made it in August 2001 because it said, "We'll allow this to go forward, and we will fund it federally, and we'll have some oversight at the NIH." The problem was that that—the lines didn't pan out. And so it's reasonable now to take another look at those limits and say, "Since we had already made the compromise of using leftover embryos, can we expand them so that the scientific basis of that original thoughtful compromise could now be expanded to be more scientifically valid, and open it to a far wider number of lines, including the new lines that have been developed, and are being developed, with better technologies?"

The scientists—and I'm not a scientist—the scientists tell me that one of the things that happens, and happens because science is global all over the world, is they're constantly developing new ways of growing these. It's a tricky business to grow these stem cell lines, and we want our American researchers to have access to the best and the freshest stem cell lines possible.

Good stuff can be done with the ones that were funded and created a number of years ago, and I want to applaud the NIH for continuing to do that work. But that's just at the very, very early beginning, and we could expand that quite easily, even within the framework already established——

Senator WYDEN. My——

Dr. ZOLOTH.—by this Administration.

Senator WYDEN.—my time is up. And that is a thoughtful response, because I think you're absolutely right, when you're in a controversial field, and people say, "All right, I'd like to start here," then you start there, and you see what happens. But what has, in fact, happened—and you have pointed this out—is, we have gotten something like a third of the number of stem cell lines——

Dr. ZOLOTH. Yes.

Senator WYDEN.—that people originally conceived of, plus another hundred are now, according to scientists, supposed to be out there. And I appreciate your answers.

And thank you, Mr. Chairman.

Senator WYDEN. Thank you.

Mr. Dorgan? We'll go in order of appearance.

STATEMENT OF HON. BYRON L. DORGAN,
U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. Mr. Chairman, thank you very much.

I did not hear the testimony of the witnesses because I was elsewhere, but I thank you for appearing.

Let me follow up on Senator Wyden's question to Mr. Doerflinger. In an in vitro fertilization clinic, there are fertilized eggs that are not used, and frozen, and then later discarded. Let me ask about the status of a fertilized egg that is now frozen at one of those clinics. Is that, "a member of the human race," as you use the term?

Mr. DOERFLINGER. Yes, Senator, it's no longer a fertilized egg; it's now an embryo that consists of, depending on when they froze it, four or eight or sixteen or maybe a hundred cells.

Senator DORGAN. So you have great angst about those being discarded, I assume.

Mr. DOERFLINGER. Well, I think it's immoral to discard a human embryo. But the embryos that parents choose to discard are not the ones available for research, obviously.

Senator DORGAN. Right. And there are now about one million children born as a result of the work at in vitro fertilization clinics. And that, it seems to me, is a process that is giving life, and it would seem to me to be pro life in its impact on our country and on the parents and on the children who are born. But your position, as I understand it, is that you do not support the in vitro fertilization. Is that correct?

Mr. DOERFLINGER. That's correct, Senator. We understand the desires of infertile couples and the good goal that's intended. But a lot of the hard questions in morality have to do with whether the means to the end are worthy of the end. And here, we have a process that basically takes reproduction away from the parents. The act of conception is done by a laboratory technician in a laboratory dish and obviously exposes these embryos to a lot of dangers of dying in the laboratory, of being discarded, of being misused for research.

Senator DORGAN. So your position is, there's an equivalency between a fertilized egg that is now frozen at an in vitro fertilization clinic and a 40-year-old person suffering from Parkinson who might—Parkinson's disease or some other disease—that might benefit from the research that comes from stem cell research. There's an equivalency. Both are, "members of the human race," and deserve equal status and equal protection. Is that fair?

Mr. DOERFLINGER. Equal protection is probably the right word. Neither of these should be killed to help anybody else.

Senator DORGAN. All right. And so your position is that those who—those fertilized eggs at an in vitro fertilization clinic are being discarded are being killed, that is the killing of a human?

Mr. DOERFLINGER. They're certainly being neglected.

Senator DORGAN. Are they being killed?

Mr. DOERFLINGER. Well, I think there's direct killing when you take the inner cells out and destroy them for research. It's more negligent when you just leave them out to thaw and die.

Senator DORGAN. I react—you know, I react strongly to those that use the term "kill" and "murder." I've heard, until I'm about sick, of the term "clone and kill," "murdering embryos," and so on. And——

Mr. DOERFLINGER. Well, I don't use the word "murder," Senator.

Senator DORGAN. I understand you didn't. But I—it's used all over the country in this debate, and I——

Mr. DOERFLINGER. How about the word "destroy"?

Senator DORGAN. Let me ask, also, about the issue of the cloning of a cell. My colleague Senator Brownback asked the question about, Do you favor human cloning? I'm not sure I understand what that question means. If it's the cloning of a human being, I assume everyone here agrees that there ought to be criminal penalties against it. If the question is to elicit an answer with respect to the cloning of a cell to—somatic cell nuclear transfer—for the purpose of embryonic stem cell research, that's a different set of issues. I don't know what the intent of the question was.

Senator BROWNBACK. Mine was to Dr. Zoloth to ask her if she supported human cloning.

Senator DORGAN. Is that the somatic cell—would that be therapeutic?

Senator BROWNBACK. That's the creation of a human being by means of the cloning process that was used to create Dolly.

Senator DORGAN. So——

Senator BROWNBACK. At the very earliest of stages.

Senator DORGAN. Then I think—but I think all of us would—we'd reach agreement on that point. We don't intend to try to create a Dolly or a human version of Dolly. So I think we all agree on that point. I think—let me just ask a couple of question of Dr. Zoloth on the question of somatic cell nuclear transfer.

We, I think, 30 years ago, in addition to having a debate about the opening of in vitro fertilization clinics and having people talk about how awful that would be and so on, we had a debate about recombinant DNA cloning back then, and the same specter of discussions back then about the fear that science was going too far, too fast. They weren't sure what would come from the Harvard laboratories, what would, "crawl out of the laboratory," was the reason one city passed an ordnance against it, and so on. And I know that that's a different type of cloning; but, nonetheless, it is a debate that we constantly have about scientific inquiry.

And let me ask you the question, whether it is using your skin cell from your earlobe through the cloning of that cell and the development of embryonic stem cells or an embryonic stem cell that's derived from a fertilized egg that's to be discarded at a clinic, is there—and I don't know that you're the right person to ask this—but is there a dramatic difference in the experience with respect to embryonic stem cells and also the promise of adult stem cells with respect to this kind of research?

Dr. ZOLOTH. These are complicated questions, and I want to try to answer them separately.

The first is, we did have a debate about recombinant DNA technology. It wasn't really cloning, but it did raise the issue of the specter of genetic manipulation. And it was resolved, in large part, because scientists, themselves, agreed to set their own limits and they established the kind of Federal guidelines that Mr. Wyden talked about at the Recombinant DNA Technology Committee that oversees, and still does oversee, recombinant DNA technology experiments.

Senator DORGAN. Can I just interrupt——

Dr. ZOLOTH. But the decline——

Senator DORGAN.—for one moment——

Dr. ZOLOTH. Yes.

Senator DORGAN.—to ask this question? My understanding about the monoclonal antibodies issue is that the development of new cancer therapies is, the cloning of cells that produce special antibodies. So there is a cloning process——

Dr. ZOLOTH. Yes.

Senator DORGAN.—in there, isn't there?

Dr. ZOLOTH. It means—cloning means doubling, means replicating. And so——

Senator DORGAN. Replicating, copying.

Dr. ZOLOTH.—in essence, it makes copies.

Senator DORGAN. Right.

Dr. ZOLOTH. The International Society of Stem Cell Research just has decided that the word "cloning," itself, can be confusing because it has so many scientific meanings—to use the words "somatic cell nuclear transfer" or "nuclear transfer" to define the thing that people are really worried about, which is taking an adult nucleus and putting into a human—in human egg and then starting the process of a new blastocyst creation at that moment.

So then you asked a second question, which is, Is there a difference in that sort of blastocyst that's created that way and in the blastocysts created through the normal gametes—two gametes mixing? And the answer is, scientifically, we don't know yet. We can't know such a thing yet. We know a few experiments in animals—obviously, not in humans, for very good reasons—and we can't yet know.

And that's the interesting thing about this early technology. It's very early. And that's why I think it's more like free speech, because the basic thing that we are thinking—or I'm—as I look over the shoulder of the scientists in the labs, as an ethicist—is, they're learning how cells signal and change and grow and die. And so growth and death and change is the basis for all human disease. Basic research is very basic. We're well before applications, but we won't get to the applications if we don't know how cells change and become from an undifferentiated cell, a pluripotent cell, into a committed cell. And that shift is a very unexplored one, and it's that exploration that this research is aimed toward.

Senator DORGAN. Just one comment, to say that I think that there are significant ethical, religious, moral issues around all of these discussions. I understand that. I think we should move carefully with regard to all of that. But, in the end, I also believe differently, for example, than Dr. Doerflinger, that things like the in vitro fertilization clinics, the advances in research, the capability to

save lives is very important, even as we think through all of these more difficult issues.

I thank you for the time.

Senator BROWNBACK. Thank you.

Mr. Ensign?

STATEMENT OF JOHN ENSIGN,
U.S. SENATOR FROM NEVADA

Senator ENSIGN. Thank you, Mr. Chairman. Thanks for having these incredibly important hearings.

And I agree with you, Senator Dorgan, that the questions raised with these issues are difficult from a moral standpoint, regardless of your viewpoint, difficult from a scientific standpoint. And so I want to explore a little bit about how we make these moral decisions.

Dr. Zoloth, you've talked about that you would be against human cloning for reproductive purposes, but then you said "but not for basic research." Am I correct in that?

Dr. ZOLOTH. That's correct.

Senator ENSIGN. How do you make the moral stand that one is OK and one isn't? In other words, where do you get your morals to judge that one is OK and one isn't?

Dr. ZOLOTH. That's a very interesting question. To what extent does my religious faith influence my moral position as a bioethicist, as an academic bioethicist?

Senator ENSIGN. Well, I don't even know if you have a religious faith. I just want to know how you make these moral decisions.

Dr. ZOLOTH. To make the distinctions, all right. In two ways. The first really is that I am—I'm guided in these issues which—like when life begins—which I believe are deeply theological, religious issues, by my position as an orthodox Jew and by the process of examination of the science by religious leadership and by scholars, in light of the text and in light of the traditional of Judaism. And so that does inform my opinion and my passion. Just as Mr. Doerflinger's position is deeply informed by his Catholic moral theology, mine is deeply informed by Judaism and the orthodox tradition from which I speak. So that's one answer.

The other answer is the years of study and research that my field, American bioethics and international bioethics, has done in taking a look at these complicated ethical and moral debates. I like good arguments from whatever religious tradition they emerge, from whatever philosophical tradition emerge. And that's how I became convinced, by listening not only to my own sources, but to the wise counsel and the gravitas of the Catholics and of the Protestants, the Buddhists, the Hindus, who all have looked at this issue with great and exquisite care. And I've come to a position that I think that human reproductive cloning is wrong in the same way that slavery is wrong, in the same way that certain forms of servitude are wrong——

Senator ENSIGN. Well, why is it wrong?

Dr. ZOLOTH. I think because of one thing that's important to me. I think it gives us a very distorted idea about the—our ideas of death. That's actually what I come down to about human cloning. I think—because our usual argument is, it's completely unsafe.

And I can't conceive of an experiment that we could prove it's safe inside the woman's body. I mean, I just can't think of a way to—even if you had hundreds of animal studies that proved it's safe, how would the first human experiments be done? As a bioethicist, it's hard to imagine the phase-one clinical trial that one could design.

But the moral issue for me is that I think it confuses us about the limits of human mortality and the limits of death itself if it's ever used to try to replace an actual human person.

Senator ENSIGN. OK.

Dr. ZOLOTH. That's the sort of confusion that I would pose.

Senator ENSIGN. And the reason I'm asking this, and I don't want to be combative—the reason I'm going down this line of questioning is because some who are in favor of embryonic stem cell research are looking at it from strictly a pragmatic point of view. You're going to help other people with the research over here, you know, and that's a greater good. That's what their morality is telling them. And then there are others that are looking at it from their moral absolute point of view, you know, saying, "This is a human being, and we shouldn't mess with it." And because we don't know these questions—you know, first rule of medicine is, "Do no harm," and if you're, you know, somebody who is looking at our Creator, you know, our first rule in that regard would be "Don't violate whatever His law is set down to us."

So it is important to grapple with these as we're going forward. And I think it's important for the entire community, regardless of which side somebody comes down on, on this issue, for people to recognize that there is a lot of internal struggle on our personal moral standpoints from this. And people do disagree, depending on their background.

But the bottom line is, this is a moral decision.

Dr. ZOLOTH. Yes.

Senator ENSIGN. It is a moral decision, and we have to figure out from where we are defining our morality. You know, I do this exercise with kids all the time in high school. You mentioned slavery is wrong. Well, why is slavery wrong? Kids will say, "Well, because, you know, it's wrong to enslave, you know, one set of people over another." And I say, "Well, why?" And they say, "Well, you know, we've, you know, decided as a, you know, society that that's wrong." And I'll ask them, I'll say, "Well, what if we decided as a society, like many societies did, that that was OK. Would it make it OK?"

The bottom line is, I bring them to a point—you have to come with certain moral absolutes. There has to be rights and wrongs.

Dr. ZOLOTH. Yes.

Senator ENSIGN. There are no rights and wrongs, and moral relativism is the way of the world, then you can justify anything. You could justify human cloning. I mean, there's no question, with moral relativism, what's wrong with human cloning? If there is no higher power to answer to this, none of this is wrong.

Dr. ZOLOTH. I completely agree with you. And what's interesting and wonderful about living in America is that we're allowed to hear the voice of that higher power in a very diverse number of ways—one hears the call of God's law in a number of ways, and then you,

as the U.S. Senate, have to decide what to do with a country that hears God's law in such complicated and divergent ways.

Senator ENSIGN. Right.

Dr. ZOLOTH. And that's where science policy comes into play, to respect that voice, to honor it, and to care for each minority view that you hear, and then——

Senator ENSIGN. The difference is that when we—as policymakers, we have to make that moral choice. I mean, that's—our laws are based on morals.

Dr. ZOLOTH. Yes.

Senator ENSIGN. So we have to—at a point, we have to say where we come down, and we have to make the call. There can be all the arguments in the world and all the discussion in the world, but, you know, the kind of—we have to then decide, based on our individual morals or the morals we represent in America, where those laws are going to come to effect.

I don't know, Mr.—I didn't give you a chance to respond to any of this conversation. If you'd like jump in—as my time is very short——

Mr. DOERFLINGER. OK, thank you very much, Senator.

Just to clarify something about cloning. The cloning—and we're not talking about monoclonal antibodies. That's just replicating cells in a culture and it doesn't have anything to do with human embryos—but there's one technique of cloning called somatic cell nuclear transfer. It makes a human embryo. There's only one such procedure available right now that people are debating. And some people have said there's a difference between reproductive cloning and therapeutic cloning. But that's really not a difference in the procedure; it's simply a difference in what you do with the embryo after you've cloned it.

Senator ENSIGN. Correct.

Mr. DOERFLINGER. Some people want to put it in a womb and get a baby. A very risky procedure, by the way. And some want to put it in a dish and destroy it for its stem cells. The distinction between the two is increasingly breaking down, for two reasons.

One is that the fertility clinics realize—and the researchers realize—that any research that advances in refining somatic cell nuclear transfer for research purposes will equally serve the wild and crazy guys who want to do this for reproductive purposes, since the technique is exactly the same.

The second way it's breaking down is that in the laboratory of the states, the new laws that have been proposed by the biotechnology industry to allow cloning for research have increasingly started changing the definition of where the distinction lies. Increasingly—and this is already passed in New Jersey—you have bills introduced, and some passed, that say, "It's not reproductive cloning unless you get a live birth." You could put that embryo in a woman's womb, you could gestate it into late fetal stages, and abort it for its tissue—which, at this point, has been done in animals—and call that "therapeutic cloning."

Cloning is allowed, and will be given state funds, under this California ballot initiative, Proposition 71. Because of their market research, they don't call it cloning; they call it somatic cell nuclear transfer. But it's exactly the same thing.

Senator DORGAN. Would the Senator yield on that point?

Senator ENSIGN. Could we have Dr. Zoloth just comment on—I mean, from what I understand from, at least, my scientific background, they are the same process, up to a point, in what he is talking about. Do you disagree with what he said, as for—up to a process, they're basically the same thing?

Dr. ZOLOTH. You create a blastocyst. That is, in fact, true. It's not a marketing campaign. It's trying to be clear about the scientific language and to really describe the process, which is taking a human nucleus, an adult nucleus, and putting it in an egg——

Senator ENSIGN. I guess—here's the simplest way to describe it. Is there any difference between—up to that point——

Dr. ZOLOTH. Yes.

Senator ENSIGN.—where you go to then use it, is there any difference between how Dolly was cloned—how Dolly was created, up to that point, and somatic cell nuclear transfer?

Dr. ZOLOTH. In humans, that question has not been fully answered, biologically. That's what I'm told, that we don't know yet. Because human biology is different from sheep biology, and we don't know clearly——

Senator ENSIGN. I'm just talking about the——

Dr. ZOLOTH. We don't know.

Senator ENSIGN.—I'm talking about the study, though, or the technique—well, now, this is a fundamental question. The technique to get to that point is the same. That is the point of it.

Dr. ZOLOTH. The technique is the same. There's no question about that.

Senator ENSIGN. OK, so—and that—yes.

Senator BROWNBACK. We've got a second panel——

Senator DORGAN. Mr. Chairman?

Senator BROWNBACK. Yes?

Senator DORGAN. Let me just, if I might, just clear up one point. I had asked the Senator if he would yield. I understand he was out of time, but I don't want the panel to leave, leaving in the air this notion of putting a cloned embryo in the uterus——

Dr. ZOLOTH. Right.

Senator DORGAN.—for the purpose of harvesting body parts. That is the most preposterous nonsense I've ever heard. Are you aware of anybody in the country that's proposing that sort of thing?

Mr. DOERFLINGER. Footnote 40 in my testimony, Senator. Three different animal trials, in each of which the animal, the cloned animal embryo, could not produce usable tissues for the transplants until they had gestated and brought it to the fetal stage. In the most recent one, conducted by Robert Lanza et al., of Advanced Cell Technology, they had to develop the cloned mouse embryo to the equivalent of the fifth to sixth month in humans, and then abort it to obtain usable cells that were used to try to repair heart damage in a mouse. The researchers declared in their press release that "This is an important new paradigm," for human therapeutic cloning.

Senator DORGAN. Well, that's not responsive to my question. We've also cloned a sheep and dairy cows, but I was asking whether you know of anybody that wants to implant a cloned embryo in

a uterus for the purpose of harvesting body parts. No one that I know of in this country has proposed that. It's preposterous.

Mr. DOERFLINGER. They are proposing it, Senator, I'm sorry.

Senator DORGAN. Who's proposing it?

Mr. DOERFLINGER. To deny it is preposterous.

Senator DORGAN. Dr. Zoloth?

Mr. DOERFLINGER. That's exactly how the New Jersey law is crafted.

Senator DORGAN. Well, that is—that is nonsense. The fact is, no one in this country——

Mr. DOERFLINGER. I agree it's nonsense, but I insist to you that it's happening, and I'll give you more documentation.

Senator DORGAN. Well, Mr. Chairman, it is a specter of this debate that is the worst, in my judgment, of this debate. It is not thoughtful.

Senator BROWNBACK. Well, this should—if—this should be able to track this, whether or not this is the case or not, and——

Mr. DOERFLINGER. I'll be very happy to——

Senator BROWNBACK.—let us get——

Mr. DOERFLINGER.—give you the supplemental documentation.

Senator BROWNBACK.—laws, and let's get a copy of the New Jersey law and put it in.

Dr. ZOLOTH. It's——

Senator BROWNBACK. And, Dr. Zoloth, if you would care to respond——

Dr. ZOLOTH. I just——

Senator BROWNBACK. And I want to go to the next panel then.

Dr. ZOLOTH. I think it's real important. Mr. Dorgan has raised a very important point. We're talking about very early basic science research. It's important not to do science fiction or to instill fear in the American public. We've had quite enough of that, I think.

No responsible researcher, no IRB, no bioethicist in this country would ever pass, support, or approve such a protocol. It is unthinkable.

Senator BROWNBACK. Have you reviewed the New Jersey law?

Dr. ZOLOTH. New Jersey law, I think, does not imply that at all.

Senator WYDEN. Mr. Chairman, before——

Senator BROWNBACK. But does the New Jersey law allow that?

Dr. ZOLOTH. No, I don't think the New Jersey law would allow that.

Senator WYDEN. Mr. Chairman?

Senator BROWNBACK. OK. Well——

Dr. ZOLOTH. It's about animal——

Senator WYDEN. That's the——

Dr. ZOLOTH.—it's about animal research. It's really quite a different category.

Senator WYDEN. Right. Before a riot breaks out——

[Laughter.]

Senator WYDEN.—that is the key point. It has not been done with respect to humans.

Dr. ZOLOTH. Right. It's not about humans.

Senator WYDEN. We are talking about animals. And I agree with the Chairman, we can have these debates in a thoughtful way. I

mean, this is—and I've been trying to make my way through footnote number 40——

[Laughter.]

Senator WYDEN.—but I think my reading of footnote number 40 that you cited, Doctor, is that it does not apply to humans. And that's why I thought the point made by Senator Dorgan was important.

Senator BROWNBACK. Let's—and we'll get a copy of the New Jersey law, and let's put it in the record, so we'll have it as part of this.

[The information referred to follows:]

§§1,2 - C.26:2Z-1
and 26:2Z-2
§3 - C.2C:11A-1

P.L. 2003, CHAPTER 203, ***approved January 2, 2004***
Senate, No. 1909 ***(First Reprint)***

AN ACT concerning human stem cell research and supplementing Title 26 of the Revised Statutes [1]and Title 2C of the New Jersey Statutes[1].

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. The Legislature finds and declares that:

a. An estimated 128 million Americans suffer from the crippling economic and psychological burden of chronic, degenerative and acute diseases, including Alzheimer's disease, cancer, diabetes and Parkinson's disease;

b. The costs of treating, and lost productivity from, chronic, degenerative and acute diseases in the United States constitutes hundreds of billions of dollars annually. Estimates of the economic costs of these diseases does not account for the extreme human loss and suffering associated with these conditions;

c. Human stem cell research offers immense promise for developing new medical therapies for these debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and potential cures for Alzheimer's disease, cancer, diabetes, Parkinson's disease and other diseases;

d. The United States has historically been a haven for open scientific inquiry and technological innovation; and this environment, combined with the commitment of public and private resources, has made this nation the preeminent world leader in biomedicine and biotechnology;

e. The biomedical industry is a critical and growing component of New Jersey's economy, and would be significantly diminished by limitations imposed on stem cell research;

f. Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and maintaining this State's leadership in biomedicine and biotechnology. Publicly funded stem cell research, conducted under established standards of open scientific exchange, peer review and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies;

g. Stem cell research, including the use of embryonic stem cells for

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1] Senate SHH committee amendments adopted November 25, 2002.

medical research, raises significant ethical and public policy concerns; and, although not unique, the ethical and policy concerns associated with stem cell research must be carefully considered; and

h. The public policy of this State governing stem cell research must: balance ethical and medical considerations, based upon both an understanding of the science associated with stem cell research and a thorough consideration of the ethical concerns regarding this research; and be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of this research.

2. a. It is the public policy of this State that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells[1] [from any source] [1], including somatic cell nuclear transplantation, shall:

(1) be permitted in this State;

(2) be conducted with full consideration for the ethical and medical implications of this research; and

(3) be reviewed, in each case, by an institutional review board operating in accordance with applicable federal regulations.

b. (1) A physician or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant and appropriate information sufficient to allow that person to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the infertility treatment.

(2) A person to whom information is provided pursuant to paragraph (1) of this subsection shall be presented with the option of storing any unused embryos, donating them to another person, donating the remaining embryos for research purposes, or other means of disposition.

(3) A person who elects to donate, for research purposes, any embryos remaining after receiving infertility treatment shall provide written consent to that donation.

c. (1) A person shall not knowingly, for valuable consideration, purchase or sell, or otherwise transfer or obtain, or promote the sale or transfer of, embryonic or cadaveric fetal tissue for research purposes pursuant to this act; however, embryonic or cadaveric fetal tissue may be donated for research purposes in accordance with the provisions of subsection b. of this section [1]or other applicable State or federal law[1].

For the purposes of this subsection, "valuable consideration" means financial gain or advantage, but shall not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of embryonic or cadaveric fetal tissue.

(2) A person or entity who violates the provisions of this subsection shall be [1]guilty of a crime of the third degree and,

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notwithstanding the provisions of subsection b. of N.J.S.2C:43-3, shall be[1] subject to a [1][civil penalty of not more than] fine of up to [1] $50,000[1][, or imprisonment for a term of not more than five years, or both,] [1] for each [1][such incident. The Commissioner of Health and Senior Services shall enforce the provisions of this subsection and may make complaints against persons violating its provisions or the rules or regulations issued thereunder and prosecute violations of same] violation[1].

[1]3. A person who knowingly engages or assists, directly or indirectly, in the cloning of a human being is guilty of a crime of the first degree.

As used in this section, "cloning of a human being" means the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual.[1]

[1][3.] 4.[1] This act shall take effect immediately.

Permits human stem cell research in New Jersey.

Senator BROWNBACK. We'll get the second panel up before we get further here. I thank both panelists very much. I think this is an excellent discussion, and one we should do more of.

First will be Dr. George Daley, Associate Professor of Pediatrics and Biological Chemistry and Molecular Pharmacology, Children's Hospital, Harvard School of Medicine out of Boston; next, Dr. David Prentice, Senior Fellow, Family Research Council in Washington, D.C.; and then Dr. Marc Hedrick, President, MacroPore Biosurgery out of San Diego, California. Delighted that all of you could join us.

Dr. Daley, thank you for being here. I'd say to all the panelists your written testimony will be put into the record. If you'd like to summarize, that's quite all right. And I think you should gather from us we like to have a good period of question and answer, if we could do that.

Dr. Daley?

STATEMENT OF GEORGE Q. DALEY, M.D., PH.D., REPRESENTING THE AMERICAN SOCIETY FOR CELL BIOLOGY

Dr. DALEY. Yes, thank you.

Senator Brownback, Members of the Committee, thank you for inviting me to testify. I am here today representing the American Society for Cell Biology, which represents over 8,000 basic biomedical researchers in the United States.

I am a physician scientist. I am clinically active in the care of children and adults with malignant and genetic diseases of the blood. I run an NIH-supported laboratory and hold grants pertinent to both adult and embryonic stem cells. We study chronic myeloid leukemia, a cancer that arises from the adult blood stem cell,

and we investigate how to coax embryonic stem cells to differentiate into blood.

My laboratory can transplant mice with blood stem cells derived entirely in vitro from embryonic stem cells. Our goal is to replicate this success using human embryonic stem cells, with the hope of someday treating patients with leukemia, immune deficiency, aplastic anemia, and genetic diseases like sickle cell.

At the core of the controversy we're discussing today are principles that are informed more by religious and moral beliefs than by scientific issues. However, the scientific issues, indeed, play an important role in the debate. As with most controversies, much misinformation and spin exists. Today, I am here to offer scientific testimony to help clarify the facts and dispel the myths surrounding competing claims in adult and embryonic stem cell research.

I will address two central scientific questions. First is research on human adult stem cells so promising that we need not pursue research with embryonic stem cells? And second is the current Presidential policy that restricts federally funded researchers to only a limited set of cell lines adequate to explore the potential of human ES cell research?

The simple, but emphatic, answer to the first question is, no. Although research on adult stem cells is enormously valuable, adult stem cells are not the biological equivalents of embryonic stem cells, and adult stem cells will not satisfy all medical and scientific needs.

Unequivocally, adult stem cells have been isolated from bone marrow, skin and mesenchyme, which would include fat, but adult stem cells do not appear to exist for all tissues of the body, especially all tissues that are ravaged by disease. Claims of stem cells for the heart, pancreas, and kidney remain controversial.

You will also hear claims that adult stem cells are highly plastic, perhaps as versatile as embryonic stem cells, and that success with adult stem cells obviates the need to study ES cells.

As an expert in both the biology of adult and embryonic stem cells, I disagree with these claims. It is the nature of adult stem cells to regenerate only a limited subset of the body's tissues. As best we can tell under normal physiology, adult stem cells do not have a measurable capacity to replenish cells beyond their tissue of origin. Therefore, asking blood stem cells to regenerate heart or liver or brain is to ask adult stem cells to betray their intrinsic nature. Like cellular alchemy, attempts to engineer adult stem cell plasticity may never succeed in a clinically practical manner.

While the differentiation spectrum of adult stem cells is restricted, it is an incontrovertible scientific fact that embryonic stem cells can form all cells in the body. Such is the natural destiny of the stem cells of the early embryo, and the reason they inspire such fascination among biologists.

Claiming that the promise of adult stem cells trumps the need to study embryonic stem cells is an opinion at the fringe, not the forefront, of scientific thinking. The American Society of Cell Biology and every other major scientific society supports the study of both adult and embryonic stem cells.

To the second question, "Is the current Presidential policy adequate to explore the potential of ES cell research," I also answer an emphatic no. Today, federally funded scientists operate under a restrictive policy that limits us to a modest number of cells generated over 3 years ago. We cannot use new lines, and, consequently, cannot take advantage of the latest tools to explore some of the most medically promising avenues. It runs contrary to the American spirit of innovation for our government to deny its scientists every advantage to push the frontiers. The President's policy is slowing research, and it's compromising the next generation of medical breakthroughs.

I recently published an article in the New England Journal of Medicine entitled "Missed Opportunities in Human Embryonic Stem Cell Research." In it, I point out that in the 3 years since the President announced his policy, over a hundred additional lines have been generated, some which model diseases like cystic fibrosis, muscular dystrophy, and genetic forms of mental retardation. What does the President say to families whose children are affected by these devastating diseases? How does the President justify his lack of support for this research? Where is the compassion in such a conservative policy?

I am the father of two young boys, Nick and Jack, ages 3 and 6. Currently, I'm taking great delight in teaching them baseball. I count my blessings for their health; more so every time I walk through the lobby of the Children's Hospital and I see the many kids in wheelchairs who will never know the excitement of running the bases or smacking a home run.

As a physician, I wholeheartedly support ES cell research, and I see it delivering the medical breakthroughs of tomorrow.

As a scientist engaged in stem cell research, I have listened intently to the voices arguing against our work. I do not accept that the interests of microscopic embryos should trump the needs of patients.

I firmly believe that our research mission, which is to advance human knowledge in the hopes of improving health and relieving human suffering, is compassionate, life-affirming, and dedicated to the highest ideals of medicine. This important work must continue, and it is in the best interest of our society for our government to support it.

Thank you.

[The prepared statement of Dr. Daley follows:]

PREPARED STATEMENT OF GEORGE Q. DALEY, M.D., PH.D., REPRESENTING THE AMERICAN SOCIETY FOR CELL BIOLOGY

Senator Brownback, members of the Committee, thank you for inviting me here today to testify before you. My name is George Daley. I am here representing The American Society for Cell Biology where I serve as a member of the Public Policy Committee. The ASCB represents over 11,000 basic biomedical researchers in the United States and in 45 other countries.

[For the record, I am Associate Professor of Pediatrics and Biological Chemistry at the Boston Children's Hospital and Harvard Medical School, Associate Director of the Children's Hospital Stem Cell Program, a member of the Executive Committee of the Harvard Stem Cell Institute, a Board member of the International Society for Stem Cell Research, and chair of the Scientific Review Committee of the Stem Cell Research Foundation. I received one of the first grants issued by the NIH for the study of human embryonic stem cells.]

I am a physician-scientist, board certified in Internal Medicine and Hematology and clinically active in the care of children and adults with malignant and genetic diseases of the blood and bone marrow. I run an NIH-supported laboratory that studies both adult and embryonic stem cells. Part of my lab focuses on the human disease Chronic Myeloid Leukemia, a cancer that arises from the adult blood stem cell. Part of my lab is investigating how to coax embryonic stem cells to differentiate into blood stem cells. My laboratory has succeeded in transplanting mice with blood stem cells derived entirely in vitro from embryonic stem cells. Our goal is to replicate this success using human embryonic stem cells, with the hope of someday treating patients with leukemia, immune deficiency, aplastic anemia, and genetic diseases like sickle cell anemia.

As the title of the hearing states, controversy surrounds the field of human embryonic stem cell research. At the core of the controversy is the fact that harvesting embryonic stem cells requires the destruction of a human embryo. If you ascribe full personhood to the earliest stages of human development, then you are vigorously opposed to embryonic stem cell research and opposed to fertility treatments that generate embryos that are the source of embryonic stem cells. In contrast, if you believe that the earliest human embryos, as microscopic balls of primitive cells, are not the moral equivalents of babies, then you are likely to be equally vigorous in supporting embryonic stem cell research because of its immense promise for understanding and treating disease. These dueling perspectives are informed more by religious and moral beliefs than by scientific principles. However, scientific issues indeed play an important role in the current debate. As with most controversies, much misinformation exists. Today, I am here to offer scientific testimony to clarify the facts and dispel the myths surrounding competing claims in adult and embryonic stem cell research.

I will address two central scientific questions: First, is research on human adult stem cells so promising that we need not pursue research with embryonic stem cells? Second, is the current Presidential policy that restricts researchers to only a limited set of cell lines created before August 9, 2001 adequate to explore the potential of human embryonic stem cell research?

The simple but emphatic answer to the first question is "no." Although research on adult stem cells is enormously promising and has already yielded clinical success in the form of bone marrow transplantation, adult stem cells are not the biological equivalents of embryonic stem cells, and adult stem cells will not satisfy all scientific and medical needs. Moreover, a great many questions about adult stem cells remain unanswered. Adult stem cells have been unequivocally isolated from bone marrow, skin, and mesenchyme, but adult stem cells do not appear to exist for all tissues of the body. Claims of stem cells for the heart, pancreas, and kidney remain controversial. You will also hear claims that adult stem cells are plastic, perhaps as versatile as embryonic stem cells, and that success with adult stem cells obviates the need to study embryonic stem cells. As an expert in both adult and embryonic stem cell biology, I take issue with these claims. It is the nature of adult stem cells to regenerate only a limited subset of the body's tissues. As best we can tell, under normal physiologic circumstances, adult stem cells do not have a measurable capacity to differentiate beyond their tissue of origin. Therefore, asking blood stem cells to regenerate heart or liver or brain is to ask adult stem cells to betray their intrinsic nature. Like cellular alchemy, attempts to engineer adult stem cell plasticity may never succeed in a clinically practical manner. I am not arguing we should not invest in some highly speculative realms of cellular engineering with adult stem cells. Indeed, we should. I am arguing however, that the promise of adult stem cells in no way obviates the need to investigate embryonic stem cells. Claiming that the study of adult stem cells should trump the study of embryonic stem cells is an opinion at the fringe and not the forefront of scientific thinking.

While the differentiation spectrum of adult stem cells is restricted, it is an incontrovertible fact that embryonic stem cells have the ability to form all cells in the body. Such is the natural endowment of the stem cells of the early embryo, and the very reason they inspire such fascination among stem cell biologists. Scientists are seeking to discover the natural mechanisms that drive formation of specific cells and tissues, so that these principles can be faithfully reproduced with embryonic stem cells in the Petri dish. I would argue that coaxing embryonic stem cells to do what comes naturally to them is more likely to prove successful in the near term than reengineering adult stem cells towards unnatural ends. The American Society of Cell Biology and every other major scientific society supports the study of both adult and embryonic stem cells.

To the second question, "Is the current Presidential policy adequate to explore the potential of human embryonic stem cell research?" I also answer an emphatic "no." Today, federally-funded scientists operate under a restrictive policy that limits the

human embryonic stem cells that can be studied to a modest number of lines generated over three years ago. With the pre-2001 vintage cell lines we can address generic questions, but are prohibited from exploiting the latest tools being developed around the Globe. It runs contrary to the American spirit of innovation for our government to deny its scientists every advantage to push the frontiers. Ultimately this will slow the pace of medical research, and compromise the next generation of medical breakthroughs. I recently published an article in the *New England Journal of Medicine* entitled "Missed opportunities in human embryonic stem cell research" [1], in which I articulated the scientific avenues that are not being adequately investigated due to the current Presidential policy. In the three years since the President announced his policy, over a hundred additional lines have been generated, many with advantageous properties that make them highly valuable to medical scientists. Some of these new lines model diseases like cystic fibrosis, muscular dystrophy, and genetic forms of mental retardation. What does the President say to families whose children are affected by these devastating diseases? How does the President justify his lack of support for this research? Where is the compassion in such a policy?

Thankfully, I am the father of two healthy boys, ages 3 and 6. I am taking great delight in teaching them baseball and watching them root for the Red Sox. (They have much to learn about heartache in the world). As a father, I count my blessings for these God-given gifts, more so every time I walk through the lobby of the Children's Hospital, and see the many kids who will never run the bases or smack a home run. As a physician, I see the mission of ES cell research as providing the greatest hope to relieve the suffering I see in many of my patients. As a scientist, I am not impervious to the expressions of ethical concern for the sanctity of the human embryo. But in our religiously plural society, I fear we may never reach an ethical consensus given the competing entities in this debate: microscopic human embryos that represent incipient human life on the one hand, desperate patients suffering from debilitating diseases on the other. From my perspective as a father, physician, and scientist, I am moved by concern for my two boys, my patients, and for the life-affirming mission of hope and promise in embryonic stem cell research.

Senator BROWNBACK. Thank you, Dr. Daley, for your presentation.

Dr. Prentice?

STATEMENT OF DR. DAVID A. PRENTICE, PH.D., SENIOR FELLOW FOR LIFE SCIENCES, FAMILY RESEARCH COUNCIL; AFFILIATED SCHOLAR, CENTER FOR CLINICAL BIOETHICS, GEORGETOWN UNIVERSITY MEDICAL CENTER

Dr. PRENTICE. Thank you, Mr. Chairman.

Mark Twain noted that, "There is something fascinating about science; one gets such wholesale returns of conjecture out of such a trifling investment of fact." This is certainly true regarding the hype and emotion surrounding the stem cell issue.

I'd like to start with some biological definitions, more of which are in my written testimony, to provide a common scientific frame of reference. This is from Patten's "Foundations of Embryology, Sixth Edition." "Almost all higher animals start their lives from a single cell, the fertilized ovum, or zygote." The time of fertilization represents the starting point in the life history or ontogeny of the individual. Thus, within the body or in the laboratory via in vitro fertilization, the first stage of development of a new individual begins with fertilization. Because it has become an area of interest, it is useful to point out that, biologically, the process of cloning, also termed somatic cell nuclear transfer, or SCNT, also produces a zygote as a starting point for development.

The President's Council on Bioethics has noted, quote "The first product of SCNT is, on good biological grounds, quite properly re-

[1] Daley GQ. Missed opportunities in embryonic stem cell research. N Engl J Med 351:627–8, 2004.

garded as the equivalent of a zygote and its subsequent stages as embryonic stages in development," end quote.

The National Academy of Sciences has also noted that embryonic stem cells can be isolated from blastocyst-stage embryos early in human development, whether produced by fertilization or by cloning, and has called those blastocysts by the same name, whether produced by either technique.

The first question we might address, then, is, Why use stem cells? Well, the short answer is to treat degenerative diseases such as heart disease, stroke, chronic lung disease, Parkinson's, and diabetes. The stem cell has two chief characteristics. It multiplies, maintaining a pool of stem cells; and, second, given the correct signal, it can differentiate into other specific cell types for use by the body.

Embryonic stem cells were first isolated in mice in 1981, and in humans in 1998. Adult stem cells were first identified in bone marrow in the 1960s, and in recent years have been found in a wide range of tissues throughout the body.

Embryonic stem cells are derived by removing the inner cell mass of the early human embryo, or blastocyst; and, in this process, the embryo is destroyed. The cells purportedly have the advantage that they can proliferate indefinitely and can form any tissue.

Scientific publications document the claim that they can proliferate for long periods of time, but the experimental basis for their potential to form any tissue relies on the cells being within the normal developmental context of the embryo.

The published literature, however, shows that claims for embryonic stem cell advantages over adult stem cells are, so far, unsubstantiated. The National Institutes of Health actually has noted, "Thus, at this stage, any therapies based on the use of human embryonic stem cells are still hypothetical and highly experimental." And also quotes, "Whether embryonic stem cells will provide advantages over stem cells derived from cord blood or adult bone-marrow hematopoietic stem cells remains to be determined." There are no current clinical treatments based on embryonic stem cells; in fact, only few and modest published successes using animal models of disease. For embryonic stem cells, there is difficulty in obtaining pure cultures of specific cell types in the laboratory dish. There is a potential for tumor formation. The cells are actually difficult to establish and maintain in culture, and they face a significant risk of immune rejection.

A recent publication from the Whitehead Institute reported that "embryonic stem cells are actually genomically unstable," meaning that the expression of their genes is unstable. And this may explain the problems in achieving true functional differentiation of embryonic stem cells.

It has been particularly troubling in terms of diabetes. Some reports suggested a fraction of embryonic stem cells could be stimulated to produce insulin. But those reports were called into question by a Harvard study that indicated the embryonic stem cells were not making insulin themselves, but were imbibing it from the culture medium in which they were grown, and then releasing it.

Another recent study found that supposedly differentiated insulin-expressing embryonic stem cells were not actually true insulin-

expressing cells, and, when injected into animals, caused tumors. Human embryonic stem cells, even the new lines, have been found to accumulate chromosomal abnormalities in culture, as well.

Commentary in the *New England Journal of Medicine* noted significant problems still facing the potential utility of embryonic stem cells, quote, "There are still many hurdles to clear before embryonic stem cells can be used therapeutically. For example, because undifferentiated embryonic stem cells can form tumors after transplantation, it is important to determine an appropriate state of differentiation before transplantation. Differentiation protocols for many cell types have yet to be established. Targeting the differentiated cells to the appropriate organ and the appropriate part of the organ is also a challenge," end quote.

And the theory that cloning, or somatic cell nuclear transfer, will produce matching tissues for transplant that will not be rejected has already been shown to be incorrect. When tested in mice, the transplanted embryonic stem cells from the cloned mouse embryo were rejected by the genetically identical host. Even Dr. James Thompson, who was the first to isolate human embryonic stem cells, has stated that cloning is unlikely to be clinically significant. And other world leaders in the embryonic stem cell field, including Australia's Alan Trounson, have echoed this.

Cloning also will require a tremendous number of human eggs, or oocytes, to produce even one embryonic stem cell line. One estimate is a minimum of 100 eggs per patient. The recent South Korean cloning of a human embryo required 242 eggs to get just one embryonic stem cell line.

There have actually been few positive published scientific reports regarding the claims put forth for embryonic stem cells. The relative lack of success should be compared with the real success of adult stem cells. A wealth of published scientific papers over the last few years document that adult stem cells are a much more promising source of cells for regenerative medicine, to actually treat patients. They do, for example, show pluripotent capacity, meaning the capacity to form most, potentially all, of the tissues of the adult body. And this capacity has been found in cells from diverse sources, including bone marrow, peripheral blood, the inner ear, and umbilical cord blood. I've attached a chart as Appendix A to my written testimony that outlines some, though not all, of the tissues from which adult stem cells have been isolated, and some of the derivatives. In fact, even liposuctioned fat has been found to contain stem cells, which Dr. Hedrick will address in a moment.

Many published references show adult stem cells can multiply in culture, retaining their ability to differentiate, and provide a sufficient numbers of cells for clinical treatments. Moreover, they've been found effective in treating animal models of disease for diseases including diabetes, stroke, spinal cord injury, Parkinson's disease, and retinal degeneration.

Moreover, adult stem cells are already being used clinically for many diseases. When I say "clinically," I mean "in patients." These include treatments for cancers, autoimmune diseases, such as multiple sclerosis, lupus, and arthritis, anemias, such as sickle-cell anemia, immune deficiencies, making new cartilage, growing new corneas to restore sight to blind patients, clinical trials for stroke,

and several groups using adult stem cells with patients to repair damage after heart attacks. In fact, Mr. Chairman, at your last hearing, you heard testimony from patients treated with adult stem cells and receiving benefit for spinal cord injury and Parkinson's disease. The adult stem cells circumvent the problems of immune rejection, and do so without tumor formation.

The mechanism is still unknown, and it's a fascinating area, for this regeneration. In some cases, the cells do seem to interconvert into other tissues. In other cases, they fuse with the tissue, such as liver, and take on the characteristics to pursue the regeneration. And, in some cases, they simply stimulate the cells already present in the tissues so the adult stem cells are not, themselves, forming the new tissue.

But as Robert Lanza, a proponent of embryonic stem cell research, has noted, quote, "There is ample scientific evidence that adult stem cells can be used to repair damaged heart or brain tissue. If it works, it works, regardless of the mechanism," end quote.

I've given you only a sampling of citations here. I have attached to my written testimony a paper prepared for the President's Council documenting over 200 references of adult stem cell successes, as well as, in the Appendix B to this testimony, a list of approximately 54 human diseases currently being treated with adult stem cells.

In summary, these adult stem cells, including umbilical-cord blood, have been shown by the published evidence to be a more promising alternative for patient treatment. Adult stem cells have proven success, not just in the dish or in the animal, but also in the patients in the early clinical trials, and they avoid the problems with tumor formation, transplant rejection, and provide realistic excitement for patient treatment.

Thank you.

[The prepared statement of Dr. Prentice follows:]

PREPARED STATEMENT OF DR. DAVID A. PRENTICE, PH.D., SENIOR FELLOW FOR LIFE SCIENCES, FAMILY RESEARCH COUNCIL; AFFILIATED SCHOLAR, CENTER FOR CLINICAL BIOETHICS, GEORGETOWN UNIVERSITY MEDICAL CENTER

Mr. Chairman, Distinguished Members of the Committee, thank you for the opportunity to provide testimony on this important subject.

Mark Twain noted that "There is something fascinating about science. One gets such wholesale returns of conjecture out of such a trifling investment of fact." This is certainly true regarding the hype and emotion surrounding the stem cell issue.

We should start with some biological definitions, to provide a common scientific frame of reference.

"Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote). . . The time of fertilization represents the starting point in the life history, or ontogeny, of the individual." [1]

The quotes below are from internationally preeminent human embryologist Ronan O'Rahilly in his latest textbook. Dr. O'Rahilly originated the international Carnegie Stages of Human Embryological Development, used for many decades now by the International Nomina Embryologica (now the Terminologica Embryologica) Committee which determines the scientifically correct terms to be used in human embryology around the world.

> "Although life is a continuous process, fertilization. . .is a critical landmark because, under ordinary circumstances, a new, genetically distinct human organism is formed when the chromosomes of the male and female pronuclei blend

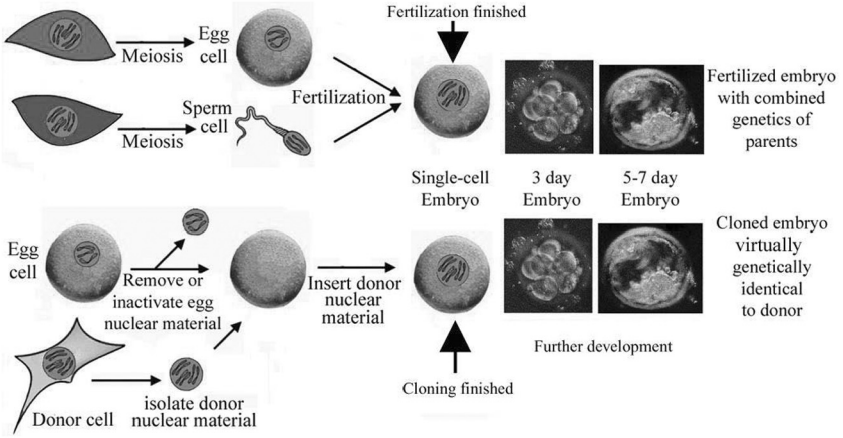
[1] Carlson, Bruce M.; Patten's Foundations of Embryology, 6th edition. New York: McGraw-Hill, 1996, p. 3

in the oocyte. This remains true even though the embryonic genome is not actually activated until 2–8 cells are present, at about 2–3 days. . . During the embryonic period proper, milestones include fertilization, activation of embryonic from extra-embryonic cells, implantation, and the appearance of the primitive streak and bilateral symmetry. Despite the various embryological milestones, however, development is a continuous rather than a saltatory process, and hence the selection of prenatal events would seem to be largely arbitrary."[2]

"Prenatal life is conveniently divided into two phases: the embryonic and the fetal . . . [I]t is now accepted that the word embryo, as currently used in human embryology, means 'an unborn human in the first 8 weeks' from fertilization. Embryonic life begins with the formation of a new embryonic genome (slightly prior to its activation)."[3]

Thus whether within the body or in the laboratory via in vitro fertilization or other assisted reproductive techniques, the first stage of development of a new individual begins with fertilization. Because it has become an area of interest, it is useful to point out that biologically the process of cloning (somatic cell nuclear transfer; SCNT) also produces a zygote as the starting point for development. As the President's Council on Bioethics has noted, "The first product of SCNT is, on good biological grounds, quite properly regarded as the equivalent of a zygote, and its subsequent stages as embryonic stages in development."[4] The National Academy of Sciences noted the following:

"The method used to initiate the reproductive cloning procedure is called nuclear transplantation, or somatic cell nuclear transfer (SCNT). It involves replacing the chromosomes of a human egg with the nucleus of a body (somatic) cell from a developed human. In reproductive cloning, the egg is then stimulated to undergo the first few divisions to become an aggregate of 64 to 200 cells called a blastocyst. The blastocyst is a preimplantation embryo that contains some cells with the potential to give rise to a fetus and other cells that help to make the placenta. If the blastocyst is placed in a uterus, it can implant and form a fetus. If the blastocyst is instead maintained in the laboratory, cells can be extracted from it and grown on their own."[5]



Embryonic stem cells can be isolated from a blastocyst-stage embryo early in human development, whether produced by fertilization or by cloning (SCNT):

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[2] Ronan O'Rahilly and Faiola Muller, "Human Embryology & Teratology", 3rd ed. New York: Wiley-Liss, 2001; p. 8

[3] Ronan O'Rahilly and Faiola Muller, "Human Embryology & Teratology", 3rd ed. New York: Wiley-Liss, 2001; p. 87

[4] "Human Cloning and Human Dignity: An Ethical Inquiry", Report of the President's Council on Bioethics, July 2002; p. 50

[5] Scientific and Medical Aspects of Human Reproductive Cloning, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Jan 2002; Preface page xii.

"[A]n embryonic stem cell (ES cell) is defined by its origin. It is derived from the blastocyst stage of the embryo. The blastocyst is the stage of embryonic development prior to implantation in the uterine wall." [6]

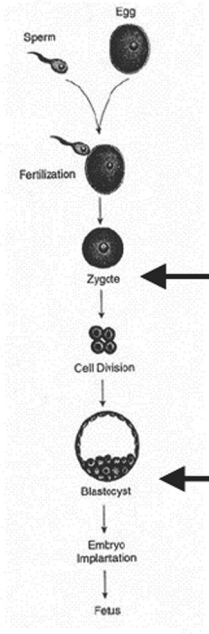


Figure 1 Stages of Development of the Human Embryo

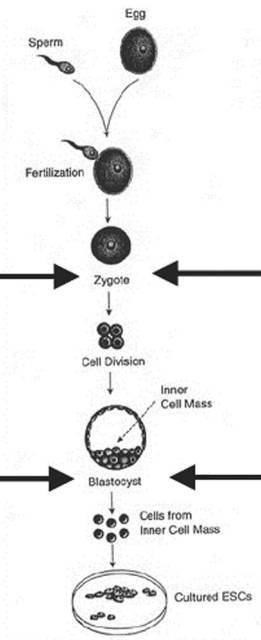


Figure 2 Isolation and Culture of Human ESCs from Blastocysts

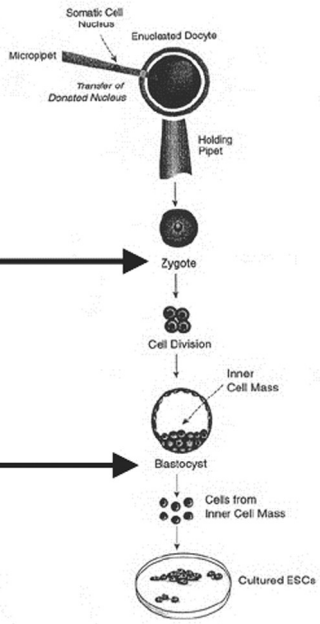


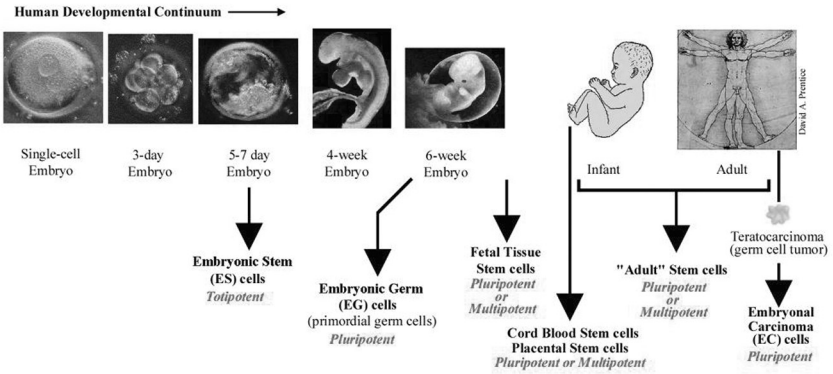
Figure 4 Somatic Cell Nuclear Tranfer (SCNT).

[From: Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Sept. 2001; Pg. 10, 11, 26]

A first question we might address is, "Why use stem cells?" The short answer is to treat degenerative diseases. In the past, infectious diseases were the scourge of mankind; antibiotics, vaccinations, and sanitation have dealt with these as killers. Today degenerative diseases, such as heart disease, stroke, chronic lung disease, Parkinson's disease, and diabetes are our main concern. These leading causes of death in the U.S. are common to all developed nations and are becoming more prevalent in developing nations. In degenerative diseases, it is usually only part of the organ or tissue that is damaged, rather than the entire organ. Stem cells are proposed to treat these diseases by repairing and replacing the damaged tissue.

[6] "Stem Cells: Scientific Progress and Future Research Directions", National Institutes of Health, June 2001; Pg. 5

Stem Cells



A stem cell has two chief characteristics: (1) it multiplies, maintaining a pool of stem cells, and (2) given the correct signal, it can differentiate into other specific cell types for use by the body. There are several sources of stem cells (see figure above). The two types which have generated the most interest are embryonic stem cells derived from the early embryo (5–7 days after conception), and so-called adult stem cells which reside in most, if not all, tissues of the body. Embryonic stem cells were first isolated in mice in 1981, and in humans in 1998; adult stem cells were first identified in bone marrow in the 1960s, and in recent years have been found in a wide range of tissues throughout the body. Adult stem cells are actually present in the tissues of the individual from the moment of birth, and could more properly be termed tissue stem cells, post-natal stem cells, or non-embryonic stem cells, and include umbilical cord blood stem cells and placental stem cells.

Embryonic stem cells are derived by removing the inner cell mass of the early human embryo (the blastocyst); in this process, the embryo is destroyed. The cells are placed into culture, and their purported advantages are that they can proliferate indefinitely, and can form any tissue. Scientific publications support the claim that they can proliferate for long periods of time in culture. In theory they can form any tissue; however, the experimental basis of their potential to form any tissue relies on the cells being within the normal developmental context of the embryo, where they form the range of tissues and organs of the human body during normal development.

While embryonic stem cells might seem to have a theoretical advantage over adult stem cells, the published literature shows that the claims for embryonic stem cell advantages over adult stem cells are thus far unsubstantiated. Indeed, the National Institutes of Health has noted that: "Thus, at this stage, any therapies based on the use of human ES cells are still hypothetical and highly experimental."[7] And also "Whether embryonic stem cells will provide advantages over stem cells derived from cord blood or adult bone marrow hematopoietic stem cells remains to be determined."[8]

There are no current clinical treatments based on embryonic stem cells, and there are in fact only few and modest published successes using animal models of disease. Those who work with embryonic stem cells even have difficulty obtaining pure cultures of specific cell types in the laboratory dish. For example, an Israeli group reported in 2001 that they had obtained insulin-secreting cells from human embryonic stem cells.[9] While this report was seized on by the press as a potential treatment for diabetes, what was not reported, and what was revealed by the scientific paper, was that only 1 percent of the cells in the culture dish supposedly made insulin. The remaining 99 percent of the cells were a mixture of other cell types, including nerve, muscle, a few beating heart cells, and also cells which continued to pro-

[7] National Institutes of Health, "Stem cells: Scientific progress and future directions", June 2001; p. 17.

[8] National Institutes of Health, "Stem cells: Scientific progress and future directions", June 2001; p. 63.

[9] Assady S *et al.,* Insulin production by human embryonic stem cells, *Diabetes* 50, 1691–1697, Aug 2001.

liferate. In fact, those growing cells point out another problem with embryonic stem cells—the potential for tumor formation.[10] Embryonic stem cells have a distinct tendency to run out of control.

Embryonic stem cells are actually difficult to establish and maintain in culture. James Thompson, who originated the first human embryonic stem cells in 1998, required 36 human embryos to finally obtain just 5 stem cell lines. Each stem cell line derives from one embryo. The Jones Institute in Virginia, in the summer of 2001, used 110 human embryos to derive 3 stem cell lines. And in the spring of 2004, a Harvard group used 342 human embryos to obtain 17 stem cell lines. In addition, embryonic stem cells face a significant risk of immune rejection. Tissue formed from embryonic stem cells will thus be rejected like most organ transplants without a precise tissue match. Indeed, a group from the Whitehead Institute reported that embryonic stem cells are actually genomically unstable, meaning that the expression of their genes is unstable: "The epigenetic state of the embryonic stem cell genome was found to be extremely unstable."[11] This might in fact explain why there is such difficulty in obtaining pure cultures and why they tend to form tumors. This may also explain the problems in achieving true functional differentiation of embryonic stem cells. This has been particularly troubling with regards to diabetes. While some reports have suggested that a fraction of embryonic stem cells could be stimulated to produce insulin, those reports were called into question by a Harvard study that indicated the embryonic stem cells were not making insulin themselves, but were imbibing it from the culture medium in which they were grown and then releasing it.[12] Another recent study found that supposedly differentiated insulin-expressing embryonic stem cells were not actually true beta cells, and when injected into animals caused tumors.[13] Human embryonic stem cells (even new lines) have been found to accumulate chromosomal abnormalities in culture as well.[14] [15]

It is illustrative to examine some quotes from proponents of embryonic stem cell research. In a review paper co-authored by James Thompson,[16] the following statements are noteworthy:

> "Rarely have specific growth factors or culture conditions led to establishment of cultures containing a single cell type."
>
> "Furthermore, there is significant culture-to-culture variability in the development of a particular phenotype under identical growth factor conditions."
>
> "[T]he possibility arises that transplantation of differentiated human ES cell derivatives into human recipients may result in the formation of ES cell-derived tumors."
>
> "[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [generation of human embryos by nuclear reprogramming] becoming a routine clinical procedure . . ."

Other researchers have noted similar problems with embryonic stem cells:

> "The work presented here shows that none of the eight growth factors tested directs a completely uniform and singular differentiation of cells."[17]
>
> "Transplanted ES cells spontaneously differentiate into any of a variety of ectodermal, endodermal and mesodermal cell types—sometimes into a disorganized mass of neurons, cartilage and muscle; sometimes into teratomas containing an eye, hair or even teeth."[18]

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[10] Wakitani S *et al.;* "Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint"; *Rheumatology* 42, 162–165; January 2003.

[11] Humpherys S *et al.;* "Epigenetic instability in ES cells and cloned mice"; *Science* 293, 95–97; 6 July 2001.

[12] Rajagopal J *et al.;* "Insulin staining of ES cell progeny from insulin uptake"; *Science* 299, 363; 17 Jan 2003.

[13] Sipione S *et al.,* "Insulin expressing cells from differentiated embryonic stem cells are not beta cells", *Diabetologia* 47, 499–508, 2004 (published online 14 Feb 2004).

[14] Cowan CA *et al.,* "Derivation of embryonic stem cell lines from human blastocysts", *New England Journal of Medicine* 350, 1353–1356, 25 March 2004; published online 3 March 2004.

[15] Draper JS *et al.,* "Recurrent gain of chromosomes 17q and 12 in cultured human embryonic stem cells", *Nature Biotechnology* 22, 53–54; January 2004.

[16] Odorico JS, Kaufman DS, Thomson JA, "Multilineage differentiation from human embryonic stem cell lines," *Stem Cells* 19, 193–204; 2001.

[17] Schuldiner M *et al.;* "Effects of eight growth factors on the differentiation of cells derived from human embryonic stem cells"; *Proc. Natl. Acad. Sci. USA* 97, 11307–11312; Oct. 10, 2000.

[18] Robert P. Lanza, Jose B. Cibelli, & Michael D. West; "Human therapeutic cloning"; *Nature Medicine* 5, 975–977; September 1999

A commentary in the journal *Science* included the following:[19]

> "[M]urine ES cells have a disturbing ability to form tumors, and researchers aren't yet sure how to counteract that. And so far reports of pure cell populations derived from either human or mouse ES cells are few and far between—fewer than those from adult cells." "Bone marrow stem cells can probably form any cell type," says Harvard's [Douglas] Melton.

And a commentary in the New England Journal of Medicine noted the significant problems still facing potential utility of embryonic stem cells:[20]

> "There are still many hurdles to clear before embryonic stem cells can be used therapeutically. For example, because undifferentiated embryonic stem cells can form tumors after transplantation in histocompatible animals, it is important to determine an appropriate state of differentiation before transplantation. Differentiation protocols for many cell types have yet to be established. Targeting the differentiated cells to the appropriate organ and the appropriate part of the organ is also a challenge."

Furthermore, the theory that cloning (SCNT) will produce matching tissues for transplant that will not be rejected has already been shown incorrect. When tested in mice,[21] the ES cells from the cloned mouse embryo were rejected by the genetically-identical host:

> "Jaenisch addressed the possibility that ES clones derived by nuclear transfer technique could be used to correct genetic defects . . . However, the donor cells, although derived from the animals with the same genetic background, are rejected by the hosts." [22]

As noted above, Dr. James Thomson has stated that cloning is unlikely to be clinically significant. Other leaders in the embryonic stem cell field have also published similar views, including Australia's Alan Trounson:[23]

> "However, it is unlikely that large numbers of mature human oocytes would be available for the production of ES cells, particularly if hundreds are required to produce each ES line . . . In addition, epigenetic remnants of the somatic cell used as the nuclear donor can cause major functional problems in development, which must remain a concern for ES cells derived by nuclear transfer . . . it would appear unlikely that these strategies will be used extensively for producing ES cells compatible for transplantation."

The evidence from animal studies indicates that it will indeed require a tremendous number of human oocytes to produce even one ES line from cloned embryos. Dr. Peter Mombaerts, who was one of the first mouse cloners, estimates that it will require a minimum of 100 eggs.[24] The reported first cloning of a human embryo in South Korea this year actually required 242 eggs to obtain just one ES cell line.[25]

There are in truth few actual positive published scientific reports regarding the claims put forth for embryonic stem cells, and a significant number of negative characteristics. At present embryonic stem cells have shown modest success in repairing spinal cord damage[26] and Parkinson's disease,[27] though the latter experiments

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[19] Vogel G, "Can Adult Stem Cells Suffice?", Science 292, 1820–1822, June 8, 2001

[20] Phimister EG and Drazen JM, "Two fillips for human embryonic stem cells," *New England Journal of Medicine* 350, 1351–1352, 25 March 2004 (published online 3 March 2004).

[21] Rideout WM *et al.,* "Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy," *Cell* 109, 17–27; 5 April 2002 (published online 8 March 2002).

[22] Tsai RYL, Kittappa R, and McKay RDG; "Plasticity, niches, and the use of stem cells"; *Developmental Cell* 2, 707–712; June 2002.

[23] Trounson AO, "The derivation and potential use of human embryonic stem cells", *Reproduction, Fertility, and Development* 13, 523–532; 2001

[24] Mombaerts P, "Therapeutic cloning in the mouse", *Proceedings of the National Academy of Sciences USA* 100, 11924–11925; 30 Sept. 2003 (published online 29 August 2003).

[25] Hwang WS *et al.,* "Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst", *Science* 303, 1669–1674; 12 March 2004 (published online 12 Feb. 2004).

[26] McDonald JW *et al.,* "Transplanted embryonic stem cells survive, differentiate and promote recovery in injured rat spinal cord," *Nature Medicine* 12, 1410–1412, Dec 1999; Liu S *et al.,* "Embryonic stem cells differentiate into oligodendrocytes and myelinate in culture and after spinal cord transplantation," *Proc. Natl. Acad. Sci. USA* 97, 6126–6131; 23 May 2000; Brüstle O *et al.,* "Embryonic Stem Cell-Derived Glial Precursers: A Source of Myelinating Transplants," *Science* 285, 754–756, 30 July 1999.

[27] Nishimura F *et al.;* "Potential use of embryonic stem cells for the treatment of mouse Parkinsonian models: improved behavior by transplantation of in vitro differentiated dopaminergic neurons from embryonic stem cells"; *Stem Cells* 21, 171–180; March 2003; Bjorklund LM *et al.;* "Embryonic stem cells develop into functional dopaminergic neurons after

showed significant tumor formation in the animals. The theoretical potential of embryonic stem cells to treat diseases, and the theoretical ability to control their differentiation without tumor formation, is wishful thinking.

The relative lack of success of embryonic stem cells should be compared with the real success of adult stem cells. A wealth of scientific papers published over the last few years document that adult stem cells are a much more promising source of stem cells for regenerative medicine. Adult stem cells actually do show pluripotent capacity in generation of tissues, meaning that they can generate most, if not all, tissues of the body. In a paper published in May 2001, the researchers found that *one* adult bone marrow stem cell could regenerate not only marrow and blood, but also form liver, lung, digestive tract, skin, heart, muscle.[28] Other researchers have found pluripotent ability of adult stem cells various sources including from bone marrow,[29] [30] peripheral blood,[31] inner ear,[32] and umbilical cord blood.[33]

The chart attached as Appendix A shows examples (not all-inclusive) of tissues from which adult stem cells have been isolated, as well as some of the derivatives from those stem cells. Bone marrow stem cells seem particularly "plastic", potentially with the ability to form all adult tissues. Even liposuctioned fat has been found to contain stem cells which can be transformed into other tissues. In point of fact, any time someone has looked in a tissue for stem cells, they have found them.

Many published references also show that adult stem cells can multiply in culture for extensive periods of time, retaining their ability to differentiate, and providing sufficient numbers of cells for clinical treatments. More importantly, adult stem cells have been shown to be effective in treating animal models of disease, including such diseases as diabetes,[34] stroke,[35] spinal cord injury,[36] Parkinson's disease,[37] and retinal degeneration.[38]

Moreover, adult stem cells are already being used clinically for many diseases. These include as reparative treatments with various cancers, autoimmune diseases

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transplantation in a Parkinson rat model," *Proc. Natl. Acad. Sci.USA* 99, 2344–2349; 19 Feb 2002.

[28] Krause DS *et al.;* "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369–377; 4 May 2001.

[29] Jiang Y *et al.;* "Pluripotency of mesenchymal stem cells derived from adult marrow"; *Nature* 418, 41–49; 4 July 2002.

[30] D'Ippolito G *et al.,* "Marrow-isolated adult multilineage inducible (MIAMI) cells, a unique population of postnatal young and old human cells with extensive expansion and differentiation potential", *J. Cell Science* 117, 2971–2981, 15 July 2004 (published online 1 June 2004).

[31] Zhao Y *et al.;* "A human peripheral blood monocyte-derived subset acts as pluripotent stem cells"; *Proceedings of the National Academy of Sciences USA* 100, 2426–2431; 4 March 2003.

[32] Li H *et al.,* "Pluripotent stem cells from the adult mouse inner ear", *Nature Medicine* 9, 1293–1299, October 2003.

[33] Kögler G *et al.,* "A new human somatic stem cell from placental cord blood with intrinsic pluripotent differentiation potential", *J. Experimental Medicine* 200, 123–135, 19 July 2004.

[34] Oh S-H *et al.,* "Adult bone marrow-derived cells transdifferentiating into insulin-producing cells for the treatment of type I diabetes," *Laboratory Investigation* published online 22 March 2004; Kodama S *et al.,* "Islet regeneration during the reversal of autoimmune diabetes in NOD mice", *Science* 302, 1223–1227; 14 Nov 2003; Hess D *et al.,* "Bone marrow-derived stem cells initiate pancreatic regeneration", *Nature Biotechnology* 21, 763–770; July 2003.

[35] Willing AE *et al.,* "Mobilized peripheral blood stem cells administered intravenously produce functional recovery in stroke", *Cell Transplantation* 12, 449–454; 2003; Arvidsson A *et al.;* "Neuronal replacement from endogenous precursors in the adult brain after stroke"; *Nature Medicine* 8, 963–970; Sept 2002; Riess P *et al.;* "Transplanted neural stem cells survive, differentiate, and improve neurological motor function after experimental traumatic brain injury"; *Neurosurgery* 51, 1043–1052; Oct 2002.

[36] Hofstetter CP *et al.,* "Marrow stromal cells form guiding strands in the injured spinal cord and promote recovery", *Proc Natl Acad Sci USA* 99, 2199–2204; 19 February 2002; Sasaki M *et al.,* "Transplantation of an acutely isolated bone marrow fraction repairs demyelinated adult rat spinal cord axons," *Glia* 35, 26–34; July 2001; Ramón-Cueto A *et al.,* "Functional recovery of paraplegic rats and motor axon regeneration in their spinal cords by olfactory ensheathing glia," *Neuron* 25, 425–435; February 2000.

[37] Liker MA *et al.;* "Human neural stem cell transplantation in the MPTP-lesioned mouse"; *Brain Research* 971, 168–177; May 2003; Akerud P *et al.;* "Persephin-overexpressing neural stem cells regulate the function of nigral dopaminergic neurons and prevent their degeneration in a model of Parkinson's disease"; *Molecular and Cellular Neuroscience* 21, 205–222; Nov. 2002; Ourednik J *et al.;* "Neural stem cells display an inherent mechanism for rescuing dysfunctional neurons"; *Nature Biotechnology* 20, 1103–1110; Nov. 2002.

[38] Otani A *et al.,* "Rescue of retinal degeneration by intravitreally injected adult bone marrow-derived lineage-negative hematopoietic stem cells", *J. Clinical Investigation* 114, 765–774, September 2004; Otani A *et al.,* "Bone marrow derived stem cells target retinal astrocytes and can promotes or inhibit retinal angiogenesis"; *Nature Medicine* 8, 1004–1010; Sept. 2002; Tomita M *et al.,* "Bone marrow derived stem cells can differentiate into retinal cells in injured rat retina"; *Stem Cells* 20, 279–283; 2002.

such as multiple sclerosis, lupus, and arthritis, anemias including sickle cell anemia, and immunodeficiencies. Adult stem cells are also being used to treat patients by formation of cartilage, growing new corneas to restore sight to blind patients, treatments for stroke, and several groups are using adult stem cells with patients to repair damage after heart attacks. Early clinical trials have shown initial success in patient treatments for Parkinson's disease and spinal cord injury. An advantage of using adult stem cells is that in most cases the patient's own stem cells can be used for the treatment, circumventing the problems of immune rejection, and without tumor formation.

The mechanism for these amazing regenerative treatments is still unclear. Adult stem cells in some cases appear capable of interconversion between different tissue types, known as transdifferentiation. In some tissues, adult stem cells appear to fuse with the host tissue and take on that tissue's characteristics, facilitating regeneration. And in some studies, the adult stem cells do not directly contribute to the regenerating tissue, but instead appear to stimulate the endogenous cells of the tissue to begin repair. Whatever the mechanism, the adult cells are successful at regenerating damaged tissue. As Robert Lanza, a proponent of embryonic stem cells and cloning has noted, "there is ample scientific evidence that adult stem cells can be used to repair damaged heart or brain tissue . . . if it works, it works, regardless of the mechanism."[39] The citations given above for adult stem cells are only a sampling, including some more recent references. A representative list of diseases currently in patient clinical trials with adult stem cells is given as Appendix B. A more complete review of the recent adult stem cell literature is appended at the end, as a paper prepared for the President's Council on Bioethics in 2003 (see: *http://bioethics.georgetown.edu/pcbe/reports/stemcell/appendix_k.html*).

In summary, adult stem cells have been shown by the published evidence to be a more promising alternative for patient treatments, with a vast biomedical potential. Adult stem cells have proven success in the laboratory dish, in animal models of disease, and in current clinical treatments. Adult stem cells also avoid problems with tumor formation, transplant rejection, and provide realistic excitement for patient treatments.

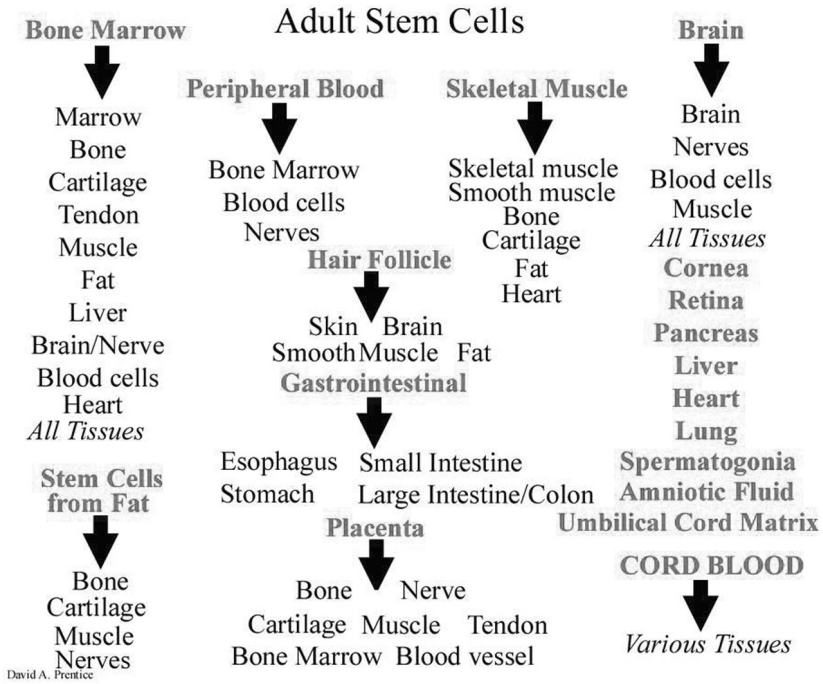
Mr. Chairman, Distinguished Members, thank you once again for allowing me to present testimony on this issue.

[39] Steve Mitchell, "Study casts doubt on adult stem cells", UPI; 12 October 2003.

APPENDIX A

Post-Natal (non-embryonic) Stem Cells and their Known or Possible Derivatives (*not* an all-inclusive list)

(From the peer-reviewed scientific literature; for placenta by company press releases)



APPENDIX B

CURRENT CLINICAL APPLICATIONS OF ADULT STEM CELLS
(NOT A COMPLETE LISTING)

ADULT STEM CELLS—HEMATOPOIETIC REPLACEMENT

CANCERS

BRAIN TUMORS—medulloblastoma and glioma

Dunkel, IJ; "High-dose chemotherapy with autologous stem cell rescue for malignant brain tumors"; Cancer Invest. 18, 492–493; 2000.

Abrey, LE *et al.;* "High dose chemotherapy with autologous stem cell rescue in adults with malignant primary brain tumors"; J. Neurooncol. 44, 147–153; Sept., 1999

Finlay, JL; "The role of high-dose chemotherapy and stem cell rescue in the treatment of malignant brain tumors: a reappraisal"; Pediatr. Transplant 3 Suppl. 1, 87–95; 1999

RETINOBLASTOMA

Hertzberg H *et al.;* "Recurrent disseminated retinoblastoma in a 7-year-old girl treated successfully by high-dose chemotherapy and CD34-selected autologous peripheral blood stem cell transplantation"; Bone Marrow Transplant 27(6), 653–655; March 2001

Dunkel IJ *et al.;* "Successful treatment of metastatic retinoblastoma"; Cancer 89, 2117–2121; Nov 15 2000

OVARIAN CANCER

Stiff PJ *et al.;* "High-dose chemotherapy and autologous stem cell transplantation for ovarian cancer: An autologous blood and marrow transplant registry report"; Ann. Intern. Med. 133, 504–515; Oct. 3, 2000

Schilder, RJ and Shea, TC; "Multiple cycles of high-dose chemotherapy for ovarian cancer"; Semin. Oncol. 25, 349–355; June 1998

MERKEL CELL CARCINOMA

Waldmann V *et al.;* "Transient complete remission of metastasized merkel cell carcinoma by high-dose polychemotherapy and autologous peripheral blood stem cell transplantation"; Br. J. Dermatol. 143, 837–839; Oct 2000

TESTICULAR CANCER

Bhatia S *et al.;* "High-dose chemotherapy as initial salvage chemotherapy in patients with relapsed testicular cancer"; J. Clin. Oncol. 18, 3346–3351; Oct. 19, 2000

Hanazawa, K *et al.;* "Collection of peripheral blood stem cells with granulocyte-colony-stimulating factor alone in testicular cancer patients"; Int. J. Urol. 7, 77–82; March 2000.

LYMPHOMA

Tabata M *et al.;* "Peripheral blood stem cell transplantation in patients over 65 years old with malignant lymphoma—possibility of early completion of chemotherapy and improvement of performance status"; Intern Med 40, 471–474; June 2001

Josting, A; "Treatment of Primary Progressive Hodgkin's and Aggressive Non-Hodgkin's Lymphoma: Is There a Chance for Cure?"; J Clin Oncol 18, 332–339; 2000

Koizumi M *et al.;* "Successful treatment of intravascular malignant lymphomatosis with high-dose chemotherapy and autologous peripheral blood stem cell transplantation"; Bone Marrow Transplant 27, 1101–1103; May 2001

ACUTE LYMPHOBLASTIC LEUKEMIA

Ohnuma K *et al.;* "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br J Haematol 112(4), 981–987; March 2001

Marco F *et al.;* "High Survival Rate in Infant Acute Leukemia Treated With Early High-Dose Chemotherapy and Stem Cell Support"; J Clin Oncol 18, 3256–3261; Sept. 15 2000

ACUTE MYELOGENOUS LEUKEMIA

Ohnuma K *et al.;* "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br J Haematol 112(4), 981–987; March 2001

Gorin NC *et al.;* "Feasibility and recent improvement of autologous stem cell transplantation for acute myelocytic leukaemia in patients over 60 years of age: importance of the source of stem cells"; Br. J. Haematol. 110, 887–893; Sept 2000

Bruserud O *et al.;* "New strategies in the treatment of acute myelogenous leukemia: mobilization and transplantation of autologous peripheral blood stem cells in adult patients"; Stem Cells 18, 343–351; 2000

CHRONIC MYELOGENOUS LEUKEMIA

Ohnuma K *et al.;* "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br J Haematol 112(4), 981–987; March 2001

JUVENILE MYELOMONOCYTIC LEUKEMIA

Ohnuma K *et al.;* "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br J Haematol 112(4), 981–987; March 2001

ANGIOIMMUNOBLASTIC LYMPHADENOPATHY with DYSPROTEINEMIA

Lindahl J *et al.;* "High-dose chemotherapy and APSCT as a potential cure for relapsing hemolysing AILD"; Leuk Res 25(3), 267–270; March 2001

MULTIPLE MYELOMA

Laughlin MJ *et al.;* "Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors", New England Journal of Medicine 344, 1815–1822; June 14, 2001

Vesole, DH *et al.;* "High-Dose Melphalan With Autotransplantation for Refractory Multiple Myeloma: Results of a Southwest Oncology Group Phase II Trial"; J Clin Oncol 17, 2173–2179; July 1999.

MYELODYSPLASIA

Ohnuma K *et al.;* "Cord blood transplantation from HLA-mismatched unrelated donors as a treatment for children with haematological malignancies"; Br J Haematol 112(4), 981–987; March 2001

Bensinger WI *et al.;* "Transplantation of bone marrow as compared with peripheral-blood cells from HLA-identical relatives in patients with hematologic cancers"; New England Journal of Medicine 344, 175–181; Jan 18 2001

BREAST CANCER

Damon LE *et al.;* "High-dose chemotherapy and hematopoietic stem cell rescue for breast cancer: experience in California"; Biol. Blood Marrow Transplant 6, 496–505; 2000

Paquette, RL *et al.,* "Ex vivo expanded unselected peripheral blood: progenitor cells reduce posttransplantation neutropenia, thrombocytopenia, and anemia in patients with breast cancer", Blood 96, 2385–2390; October, 2000.

Stiff P *et al.;* "Autologous transplantation of ex vivo expanded bone marrow cells grown from small aliquots after high-dose chemotherapy for breast cancer"; Blood 95, 2169–2174; March 15, 2000

Koc, ON *et al.;* "Rapid Hematopoietic Recovery After Coinfusion of Autologous-Blood Stem Cells and Culture-Expanded Marrow Mesenchymal Stem Cells in Advanced Breast Cancer Patients Receiving High-Dose Chemotherapy"; J Clin Oncol 18, 307–316; January 2000

NEUROBLASTOMA

Kawa, K *et al.;* "Long-Term Survivors of Advanced Neuroblastoma With MYCN Amplification: A Report of 19 Patients Surviving Disease-Free for More Than 66 Months"; J Clin Oncol 17:3216–3220; October 1999

NON–HODGKIN'S LYMPHOMA

Tabata M *et al.;* "Peripheral blood stem cell transplantation in patients over 65 years old with malignant lymphoma—possibility of early completion of chemotherapy and improvement of performance status"; Intern Med 40, 471–474; June 2001

Josting, A; "Treatment of Primary Progressive Hodgkin's and Aggressive Non-Hodgkin's Lymphoma: Is There a Chance for Cure?"; J Clin Oncol 18, 332–339; 2000

Kirita T *et al.;* "Primary non-Hodgkin's lymphoma of the mandible treated with radiotherapy, chemotherapy, and autologous peripheral blood stem cell transplantation"; Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 90, 450–455; Oct. 2000

Yao M *et al.;* "Ex vivo expansion of CD34-positive peripheral blood progenitor cells from patients with non-Hodgkin's lymphoma: no evidence of concomitant ex-

pansion of contaminating bcl2/JH-positive lymphoma cells"; Bone Marrow Transplant 26, 497–503; Sept. 2000

HODGKIN'S LYMPHOMA

Josting, A; "Treatment of Primary Progressive Hodgkin's and Aggressive Non-Hodgkin's Lymphoma: Is There a Chance for Cure?"; J Clin Oncol 18, 332–339; 2000

RENAL CELL CARCINOMA

Childs R *et al.,* "Regression of Metastatic Renal-Cell Carcinoma after Nonmyeloablative Allogeneic Peripheral-Blood Stem Cell Transplantation", New England Journal of Medicine 343, 750–758; Sept. 14, 2000

Childs, RW; "Successful Treatment of Metastatic Renal Cell Carcinoma With a Nonmyeloablative Allogeneic Peripheral-Blood Progenitor-Cell Transplant: Evidence for a Graft-Versus-Tumor Effect:; J Clin Oncol 17, 2044–2049; July 1999

VARIOUS SOLID TUMORS

Nieboer P *et al.;* "Long-term haematological recovery following high-dose chemotherapy with autologous bone marrow transplantation or peripheral stem cell transplantation in patients with solid tumours"; Bone Marrow Transplant 27, 959–966; May 2001

Lafay-Cousin L *et al.;* "High-dose thiotepa and hematopoietic stem cell transplantation in pediatric malignant mesenchymal tumors: a phase II study"; Bone Marrow Transplant 26, 627–632; Sept. 2000

Michon, J and Schleiermacher, G. "Autologous haematopoietic stem cell transplantation for paediatric solid tumors", Baillieres Best Practice Research in Clinical Haematology 12, 247–259, March-June, 1999.

Schilder, RJ *et al.;* "Phase I trial of multiple cycles of high-dose chemotherapy supported by autologous peripheral-blood stem cells"; J. Clin. Oncol. 17, 2198–2207; July 1999

SOFT TISSUE SARCOMA

Blay JY *et al.;* "High-dose chemotherapy with autologous hematopoietic stem cell transplantation for advanced soft tissue sarcoma in adults"; J. Clin. Oncol. 18, 3643–3650; Nov 1 2000

ADULT STEM CELLS—IMMUNE SYSTEM REPLACEMENT

AUTOIMMUNE DISEASES

SCLEROMYXEDEMA

Feasel *et al.,* "Complete remission of scleromyxedema following autologous stem cell transplantation," Archives of Dermatology 137, 1071–1072; Aug. 2001.

MULTIPLE SCLEROSIS

Mancardi GL *et al.;* "Autologous hematopoietic stem cell transplantation suppresses Gd-enhanced MRI activity in MS"; Neurology 57, 62–68; July 10, 2001

Rabusin M *et al.;* "Immunoablation followed by autologous hematopoietic stem cell infusion for the treatment of severe autoimmune disease"; Haematologica 85(11 Suppl), 81–85; Nov. 2000

Burt, RK and Traynor, AE; "Hematopoietic Stem Cell Transplantation: A New Therapy for Autoimmune Disease"; Stem Cells17, 366–372; 1999

Burt RK *et al.;* "Hematopoietic stem cell transplantation of multiple sclerosis, rheumatoid arthritis, and systemic lupus erythematosus"; Cancer Treat. Res. 101, 157–184; 1999

CROHN'S DISEASE

Burt RK *et al.,* "High-dose immune suppression and autologous hematopoietic stem cell transplantation in refractory Crohn disease", *Blood* 101, 2064–2066, March 2003

Rabusin M *et al.;* "Immunoablation followed by autologous hematopoietic stem cell infusion for the treatment of severe autoimmune disease"; Haematologica 85(11 Suppl), 81–85; Nov. 2000

Hawkey CJ *et al.;* "Stem cell transplantation for inflammatory bowel disease: practical and ethical issues"; Gut 46, 869–872; June 2000

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SPINAL CORD INJURY

See July 14, 2004 Senate testimony by Dr. Jean Peduzzi-Nelson:
http://commerce.senate.gov/hearings/testimony.cfm?id=1268&wit__id=3671
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For appended review paper on adult stem cells, see
http://bioethics.georgetown.edu/pcbe/reports/stemcell/appendix__.html

Senator BROWNBACK. Thank you, Dr. Prentice.
Dr. Hedrick, thank you for joining us today.

STATEMENT OF MARC HEDRICK, M.D., PRESIDENT, MACROPORE

Dr. HEDRICK. Mr. Chairman, Mr. Wyden, thank you for allowing me to be here today.

I've been fortunate to be have been involved on the front lines of the stem cell debate for some time. As a surgeon at UCLA, I saw, firsthand, the need for stem cell treatments in my patients. As a researcher, I received NIH funding while doing stem cell research at UCLA in our laboratory. And now I serve as President of MacroPore Biosurgery, a San Diego-based biotechnology company that's dedicated to developing adult stem cell therapies to help as many patients as we can.

Based on this experience, I feel like I can say to you, in the strongest possible terms, we truly are on the edge of a new frontier in medicine. Over the past 2 years, our company has made a strategic decision to try to take a leadership role in developing adult stem cell therapies. This decision was based both on our excitement for the technology, but also our vision for what we think it can do for patients.

If I may, permit me to quote from the NIH, "Given the enormous promise of stem cells to develop new therapies for the most devastating diseases when a readily available source of stem cells is identified, it is not too unrealistic to say that this research will revolutionize the practice of medicine and improve the quality and the length of life." And that's absolutely our goal. We agree with the NIH that cell availability has been a significant challenge, not only for the clinical, but for the commercial application of stem cells.

Stem cells have been thought to be rare, difficult to obtain, and requiring long periods of cell culture or multiplication. But today we have found a potential solution to some of the significant challenges particularly related to cell availability. We believe the solution is the use of fat or adipose tissue as the source of stem cells. It's a low-cost, high volume alternative to other stem cell sources. This technology enables us to rethink how patients might be treated using their own stem cells. It's an important breakthrough in stem cell technology.

From adipose, we can obtain at least two of the key types of adult stem cells that could potentially treat many diseases. Heart disease, stroke, injured bones and joints, vascular disease, degenerative spinal disease are all diseases that are in our target area.

The first adult stem cells, though, were identified 40 years ago. Since then, bone-marrow transplants have been very common for treating things like blood diseases and for cancers.

And only until recently, bone marrow was thought to be the only significant clinical reservoir of stem cells in the adult. But even this source yields a relatively few number of stem cells.

So how does adipose or fat tissue measure up as a stem cell source? Well, about a cup of adipose tissue translates into about a million stem cells. That's about a hundred times more stem cells found in the same amount of bone marrow.

And let me use myself as an example to, sort of, illustrate this.

Senator BROWNBACK. A cup has a hundred million—did you say a hundred million stem cells, a cup of fat?

Dr. HEDRICK. About a million stem cells.

Senator BROWNBACK. A million. Wow. No wonder it grows so easy. I'm sorry, go ahead.

[Laughter.]

Dr. HEDRICK. We haven't solved that problem yet.

Senator BROWNBACK. Yes.

[Laughter.]

Dr. HEDRICK. But I'm six feet one inch tall, weigh about 180 pounds, and about 15 percent of my body weight is fat tissue. That translates to about 27 pounds of fat, which equals about six billion stem cells.

What does this mean? I think it means opportunities, many opportunities, potentially, to use your own body to heal different problems and diseases that you have, but not stem cells have been obtained in weeks or months, but stem cells that can be obtained in about an hour.

And so what we're talking about with adipose-derived stem cells is using stem cells in real time without cell culture. This realtime approach is not just conceptual. At this meeting—this week at a cardiology meeting in Washington, D.C., our company, along with our collaborators at UCLA and Cedar Sinai, reported the use of adipose-derived stem cells, and noted that they are safe and improved heart function after heart attacks. We used pigs in this study, because they're predictive of future success in the treatment of heart attacks.

Heart disease is fast becoming the most promising area for the use of stem cell therapy. In 15 years, cardiovascular disease is going to be the principal cause of death worldwide, not just in the U.S. Over a million Americans each year have a heart attack, and another six million Americans right now have heart failure. Sadly, this means that one out of three people in this room are going to die from heart disease. It's a staggering thought.

And MacroPore is addressing this clinical need by developing a unique system that enables doctors to take the patient's stem cells and then treat them in real time. If successful, the system will fundamentally be state-of-the-art for heart attack treatment. It will enable us to move from supportive care, which is really all we have to offer patients now, to regenerative therapy.

Both our research and the research of our collaborators and others have found out that adult stem cells can do three important things for the failing heart. It can make new heart cells, it can make new blood vessels, and it can rescue dying heart muscle. While the science is obviously complex and there's still a lot to learn, for the doctor and the patient the procedure represents a relatively simple way to help heal the heart.

Seven clinical studies, most of them clinician-initiated studies, are now in progress around the world to study adult stem cells for cardiovascular disease, and the early results are promising. For example, follow up data just presented from the Joint Texas Heart Institute and Brazilian Heart Failure Stem Cell Human Trial noted that four out of five patients being studied were no longer in need of a heart transplant. Those patients were treated with adult bone-marrow stem cells.

But despite all the clinical successes of adult stem cells, misconceptions are still commonplace. For example, in a recent study

of Americans who claim to be knowledgeable about adult stem cells, 68 percent thought that adult stem cells come from embryos. But there are other misconceptions that perhaps are more subtle. Some think that adult stem cells are too rare, don't multiply well enough, or are too limited in their potency to ever be useful.

But all of these misconceptions are just that, they're misconceptions. The truth is that bone-marrow and adipose tissue are clinically promising sources of adult stem cells, they grow well in the petri dish, and they have the ability to make and repair many types of tissues throughout the body.

So I think we often make the mistake of referring to "the promise of stem cells," like it's some future event. And, in fact, this promise has already become a reality. The list of successful therapies that are being treated with adult stem cells grows every year, as does the list of patients' health.

While there's still a tremendous amount of work to be done—and I don't want to belittle this—I would humbly remind you that, in many cases, the promise of adult stem cells is already being realized.

Thank you.

[The prepared statement of Dr. Hedrick follows:]

PREPARED STATEMENT OF MARC HEDRICK, M.D., PRESIDENT, MACROPORE

Mr. Chairman, Distinguished Members of Committee, I would like to thank you for the opportunity to be here today.

I have been fortunate to have been on the front lines of the stem cell issue. As a surgeon at UCLA, it was easy to recognize the need for stem cell treatments in my patients, as a researcher, I received NIH funding to study adult stem cells through our program at UCLA and now as President of MacroPore, a public company located in San Diego, California our group is focused on developing adult stem cell therapies for as many people as possible. Based on this diverse experience, I feel I can say to you in the strongest possible terms, we truly are on the edge of a new frontier in medicine.

Over the past 2 years, our company, has made a strategic decision to take a leadership role in developing adult stem cell therapies. In large part this decision is based our excitement and vision for what our technology will be able to do for patients whom may benefit from stem cell therapies.

According to an official statement of the NIH in May 2000:

> ". . . given the enormous promise of stem cells to the development of new therapies for the most devastating diseases, when a readily available source of stem cells is identified, it is not too unrealistic to say that this research will revolutionize the practice of medicine and improve the quality and length of life."

That certainly is our goal.

We recognize that cell availability has been the most significant unsolved problem for the clinical application of stem cells. Stem cells have been thought to be rare, difficult to obtain, often requiring long periods of cell culture.

Today, we have found a potential solution to the significant challenge of cell availability. The solution is the use of fat tissue as a source of stem cells. I know we are all familiar with having a little too much fat tissue. With this low cost, high volume alternative to other stem cell sources, we are able to rethink how patients can be treated using their own stem cells. We view this as an important new breakthrough in adult stem cell research.

From this tissue source, we can obtain large numbers of at least 2 of the key varieties of adult stem cells: *mesenchymal stem cells* and *endothelial progenitor cells.* The resulting implication is that fat tissue is a plentiful source of stem cells that potentially can treat many diseases such as heart disease, stroke, injured bones and joints, degenerative spinal disease and vascular diseases, to name a few of the disorders researchers are currently studying.

As you know, stem cells are unique cells that have 2 well established properties: they have the ability to make more stem cells through cell multiplication, and they can mature into differentiated cells or tissues. The first adult stem cells were identified approximately 40 years ago and have been extensively studied and used to treat many diseases, particularly blood diseases or cancer, through bone marrow transplants. Later, in the 1990s, adult stem cells were then identified broadly in many organs and tissues, but in small numbers. They had to be multiplied in Petri dishes to collect large enough batches of cells to be useful, which could take many weeks.

Until today, bone marrow was thought to be the only significant clinical reservoir of adult stem cells. But it too yields only a limited number of cells.

Believe it or not, a few ounces of fat, or less than a cup, can yield approximately 1 million stem cells. This is about 100x more stem cells found in the same amount of bone marrow.

There is no shortage of fat either. According to scientific calculations, Americans carry 30 pounds of fat tissue around with them. Conceptually, it is important to understand that dosing stem cells for patients will be like giving aspirin to patients with headaches.

If you do not give them aspirin, their headache will not get better.

It is the same with stem cells, if they don't get enough stem cells, they won't get better.

In fact, this week at a meeting of cardiologists here in Washington, our Company in conjunction with UCLA and Cedar& Sinai Medical Center reported that fat derived stem cells are safe and improve heart function after heart attacks in pigs-which is animal model that is most predictive of future success in the treatment of human heart attacks.

And here's what that really means for all of us. Heart attack patients can be treated with their own stem cells soon after they arrive in the emergency room. Time is critical in the treatment of heart attack. The longer the delay in treatment, the more complex and difficult the stem cell treatment becomes.

However, with fat as a stem cell source, we can retrieve a therapeutic dose of cells, all in about an hour, not the weeks that cell culturing can take. We can treat patients in "real time".

Heart disease is becoming the most promising emerging area for the use of stem cell therapy. The timing is fortunate, because in 15 years, cardiovascular disease will supplant infectious disease as the principle cause of death worldwide. Sadly, one in 3 of us in this room will die of cardiovascular disease. A rather staggering thought. Over 1 million Americans each year have a heart attack and another 6 million have significant heart failure. Compounding the need is the fact that the efficacy of heart failure drugs seems to be at a plateau. Despite the prevalence, only 8 percent of drug discovery investment is going to cardiovascular disease.

The stem cell system that MacroPore is developing for treating heart patients is unique in its ability to treat the patient with their own stem cells immediately without waiting for someone else's cells to grow in a Petri dish.

Here's what it means in a real life situation.

If someone was unfortunate enough to have a heart attack today, that person would develop severe pain below the breast bone and be brought immediately by ambulance to the hospital. If the examination and lab tests confirm the heart attack, the cardiologist will immediately move the patient into a cardiac catheterization suite, where through a small catheter, dye will be injected into the heart so areas of blood vessel blockage can be seen and treated with a balloon or stent. This is called the angiogram procedure. Except for the addition of some standard heart medications, this is essentially the state-of-the-art for heart attack treatment.

However, with the availability stem cells derived from fat tissue, the cardiologist will soon be able to take the patient's own stem cells and reinject them directly through the angiogram catheter into the heart in about an hour. While the science is complex, for the doctor and patient the procedure represents a truly simple way to help heal the heart.

This 'global epidemic' of cardiovascular disease corresponds to a significant opportunity for stem cell therapies. Many groups worldwide are leveraging the safety and efficacy profile of adult stem cells for this epidemic.

Seven clinical studies, mostly clinician initiated, are now in progress globally to study adult stem cells in cardiovascular disease, and an estimated 150+ patients have been treated thus far. Phase II efficacy trials are underway and early results are promising. If the improvements in cardiac function now being seen hold true, previous data suggests this may result in lower hospital utilization rates, decreased hospital readmission rates and possibly removal of patients from the transplant list. Therefore, while most importantly having the potential to prolong life, adult stem cells may soon save some of the $18B spent each year on heart failure.

In fact, last week, in follow up data to the Texas Heart Institute/Pro-Cardiac Hospital stem cell trial, Dr. Hans Fernando Dohmann, coordinator of the research noted four out of five patients being studied no longer needed transplants after being treated with stem cells. He said, "It was the first time we saw that stem cells actually generate new arterioles" he went on to say that, "[stem cells] eliminated the need for transplants in four patients who had had indisputable transplant indications."

The success we are seeing in the treatment of cardiovascular disease should come as no surprise. Adult stem cells treatments have been commonplace in medicine for decades. Furthermore, it is the daily job of adult stem cells to sustain, renew, heal and in some circumstances regenerate human organs and tissues over one's entire life.

For decades, doctors have, sometimes intuitively, taken adult stem cells from one part of the body and transplanted them to another area to help patients. We have given these operations names like skin grafting, bone marrow transplantation, and bone grafting, but make no mistake-these operations achieve durable results in part by virtue of transplanting adult stem cell populations.

But despite the daily clinical successes of adult stem cells, misconceptions are commonplace. For example, in a recent study of Americans who claim to be knowledgeable about stem cells, 68 percent claim adult stem cells are from embryos. More subtle misconceptions include the idea that stem cells are too rare, don't multiply well or are too limited in their potency to be useful. All of these misconceptions are just that, they are not factually correct. The truth is that both bone marrow and fat tissue are plentiful and clinically promising sources of adult stem cells. They both multiply well, and increasingly more and more research shows that adult stem cells have the ability to make many cell and tissue types throughout the body.

We often make the mistake of referring to the promise of stem cells as if it is a future event. In fact, this 'promise' has become a reality. The list of successful therapies using adult stem cell grows yearly as does the list of patients cured. While there is still much work to be done, I would humbly remind you that in many cases the 'promise' has already been realized.

Senator BROWNBACK. Thank you.

Let me—I want to probe in this some more. So you're saying use the fat tissue stem cells in a broad array of places in the body. And I take it what you're suggesting is that this is going to be the new source of bone marrow; I mean, that what we've been doing in bone marrow, you can do with fat tissue stem cells. Is that correct? Kind of in layman's terms, is that——

Dr. HEDRICK. It is possible that, with further research, we could show that fat tissue is equal to bone marrow as a source of adult stem cells. But bone marrow's been around for about 40 years, and there's a lot of very good research for that. And we've only been around for about 5 years, and we're, sort of, catching up. So I think the jury is still out on just how significant adipose is as a source of stem cells.

Senator BROWNBACK. Now, the heart trials you were talking about, the seven or eight clinical trials going on around the world, where damaged heart tissue, dead heart tissue, is being regenerated with stem cells, that's all being done through bone marrow stem cells. Is that correct?

Dr. HEDRICK. Yes, sir. All that study's being—all the studies are being done with either bone marrow stem cells or stem cells that have been tricked out of the bone marrow by giving the patient a drug and then removing the blood from the patient several days later.

Senator BROWNBACK. But it's showing great promise, great success, a number of these people are getting off the transplant lists, their heart is—what, the fracture rate? What do they call that, the pumping rate of the——

Dr. HEDRICK. Ejection fraction.

Senator BROWNBACK. I'm not a scientist, but I've listened to enough of this that I'm getting closer. That that's really growing, doing well.

You were saying that you have an animal trial, though, that shows that you can do this with fat stem cells. Is that correct?

Dr. HEDRICK. Yes, sir. There actually have been one reported, and now our trial, that show that stem cells from adipose tissue make the heart function better. You talk about pumping ability; that's called ejection fraction. And the early results—again, these are in pigs, not in humans, and we have to make sure they translate—that we're seeing somewhere in the neighborhood of a 20 to 30 percent improvement in the pumping ability of the heart.

Senator BROWNBACK. What about the—one of the beefs on adult stem cells for some period of time has been the plasticity. And, Dr. Daley, you may want to jump on this. But it's saying these just aren't——

Dr. DALEY. Yes.

Senator BROWNBACK.—we don't think you can do this. But, Dr. Hedrick—let me get him first, and then I'll bounce over to you, happily—you're saying that with the fat tissue, you believe the plasticity is there for these to be able to treat a whole host of different types of needs within the body.

Dr. HEDRICK. Well, I——

Senator BROWNBACK. What do you base that upon?

Dr. HEDRICK. I can only speak to the science. And we, our group, and many others around the world have published the fact that there are nine or ten different kinds of cell types that can come from adipose tissue or fat tissue.

Senator BROWNBACK. Nine of ten.

Dr. HEDRICK. Nine or ten different types of cells.

Senator BROWNBACK. OK.

Dr. HEDRICK. Effectively everything we've looked for in a meaningful way, we've been able to show.

The research in heart, though, is interesting. And this is really a new area, not only for us, but others. And we really haven't shown that—in humans or in animals—that we can get heart differentiation, but we've shown it in the petri dish, and we've shown it in rodents, and other people have shown the same thing.

Senator BROWNBACK. So that you believe that the plasticity is not an issue on this type of stem cell, the fat tissue stem cells. Is that correct?

Dr. HEDRICK. Well, I believe that of the things that we've done so far, there's a high likelihood that these cells could be clinically useful. But I can't speak to the other 180 different tissue types, the cell types in the body. But what I'm saying is, these cells are on par, in terms of their plasticity, seemingly, with bone marrow.

Senator BROWNBACK. Dr. Daley?

Dr. DALEY. Yes, I—the science behind cardiovascular regeneration is a perfect case in point where the claims are getting way ahead of the actual scientific reality. It's a very seductive possibility that bone-marrow cells or fat cells injected into the heart is going to regenerate the failing heart muscle.

In fact, where it has been looked at very carefully, no heart-muscle cells are actually regenerated at all. The data that suggests there's an effect on the function of the heart is fairly reliable and reproducible in many centers around the world. But it's becoming, I think, increasingly clear—and in data that was presented at this same that Dr. Hedrick referred to—it may not be the cells themselves, but rather factors that are liberated from the cells—cytoprotective or cytokine or growth factors—that actually save the dying heart muscle in the various animal models. Whether or not this will translate into effective human therapies, I think, is really still an open question.

So it may be that the stem cells aren't there as—for plasticity at all; but, rather, to produce these other proteins, and I——

Senator BROWNBACK. But, for whatever reason——

Dr. DALEY.—think that where we're going to move is identifying those factors and to deliver them with other means not involving stem cells.

Senator BROWNBACK. But, for whatever reason, it's working. You believe, in these trials, it appears to be something that's happening positive in the pump rates of these people is working.

Dr. DALEY. Something is happening. But whether or not it's a fat stem cell or a bone-marrow stem cell becoming a heart muscle, I think is highly unlikely.

Senator BROWNBACK. But the heart is improving. They're taking them off——

Dr. DALEY. That's right.

Senator BROWNBACK.—transplant——

Dr. DALEY. So the way the science should go is to be very careful about how you design the experiments, to determine whether it's the cells or the things the cells are making which are actually having the beneficial effect on the heart.

Senator BROWNBACK. I understand. I also understand, if I'm a heart patient, what I care about is that this is working. And I understand you, from the scientist—your point of view.

The tumor issue, Dr. Daley, I want to address that, because that has come up previously in other work, other policy issues that have come up. In 1993—and you maybe familiar with this—we started down the road of funding fetal tissue use—aborted fetuses, use the fetal tissue. A lot of the claims being made then are being made now in embryonic stem cell. And I think that's—so that's always part of the cynicism and the debate.

And I've got a series of quotes from people in 1993 that this is going to cure Parkinson's and Alzheimer's and all sorts of things with fetal tissue research—or fetal tissue transfer. And the issue then—and it seemed as if what happened at that point in time—they did a series of clinical trials, series of applications, and these were just not—they were not stable cells. I believe, in the New York Times, they had a series of articles on this, that once implanted in the brain, they were forming some—forming some brain tissue, but some were forming hair, some were forming—were developing fingernails, some were developing tumors.

This—here's a question that I've wrestled with, is, that's a further-down-the-line development than what you're working on right now. You're at the embryonic—so you're even earlier—you're at an

earlier growth stage. You're at a—it seems to me, as a layman, a less stable stage of this cell's development. It'll rapidly grow, but it'll make everything, and that's the real problem. It didn't work there, and what makes you think it will not form tumors now, when you've backed up to even an earlier stage?

Dr. DALEY. Well, we would all have to be very careful and look for that very risk. There's no doubt that undifferentiated embryonic stem cells, when put into an animal, will form a form of benign encapsulated tumor, called the teratoma. And I think everybody who is involved in embryonic stem cell transplantation strategies is going to be prepared to look for that and hope it doesn't happen.

Now, the goal in ES research is to pre-differentiate the cells to a stage where they could be, then, characterized and isolated and purified free of these tumor-forming cells.

I should point out that this issue of genomic and epigenetic instability that Dr. Prentice referred to, and that is often referred to in the ES cells, is a characteristic of all cells that are kept for long periods in culture. In fact, I think it's rather remarkable that embryonic stem cells are as stable as they are in their immortal state, because, for most cells, getting things to grow in a petri dish actually involves significant chromosomal or genetic changes.

So we're all aware of this issue. We do not think it's going to be a deal-breaker for bringing these types of cells into clinical therapies.

Senator BROWNBACK. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. Prentice, several hours ago, when we began, I noted that there was an important article in the Washington Post a couple of days ago——

Dr. PRENTICE. Yes, sir.

Senator WYDEN.—outlining these new studies that show that human embryonic stem cells are showing great promise in some key areas, particularly vision. I want to be clear, are you saying that the published peer-reviewed results, like those that are cited in the article that I have mentioned with respect to embryonic stem cells, are you saying that these articles are off-base, that they're invalid?

Dr. PRENTICE. I'm not saying they're off-base, Senator. What I'm saying is, if you look at the articles carefully, in terms of how much success have they achieved, especially if our goal is regenerating tissue for disease damage, if you read, for example, the article about the vision regeneration, what Dr. Lanza and his team at Advanced Cell Technology did was achieve—for the first time, I might note—differentiation of the specific cell type from human embryonic stem cells. He calls it an RPE, retinal pigmented epithelial cell. Now, this was all done in the dish. He actually got some of them to coalesce together. I think he notes, perhaps, in the article, they looked like little eyes coalescing together. Probably not. But it's interesting that they showed that characteristic. He did not, at least in terms of the peer-reviewed report, test the ability of these cells to treat any kind of retinal degeneration.

I'd note that Mr. Weiss failed to report, in the Post, a paper that came out just 2 weeks ago in which a group at UCLA School of Medicine reported that they had actually rescued or repaired ret-

inal degeneration by injecting adult bone marrow stem cells into the eyes of mice suffering from a similar type of condition as Dr. Lanza has proposed to treat. There actually have been two other previous adult stem cell studies where they were doing the same thing for models of macular degeneration. As we age, our retinas tend to break down, retinitis pigmentosa, which is another similar condition.

So what I'm saying, Senator, is——

Senator WYDEN. You're saying that there's no problem with the validity of this study. I just want to move on. You——

Dr. PRENTICE. No, the——

Senator WYDEN.—you'd like——

Dr. PRENTICE. No, the scientific evidence——

Senator WYDEN.—you'd like some——

Dr. PRENTICE.—is there.

Senator WYDEN.—you'd like some other——

Dr. PRENTICE. It's just about 3 years behind.

Senator WYDEN.—and you'd like some other studies to be made a part of the record, as well. Is that——

Dr. PRENTICE. I would hope that Dr. Lanza would now show us that those cells could achieve the same type of success in animals, safely, as the adult stem cells.

Senator WYDEN. Another question for you, Dr. Prentice. Are you opposed to in vitro fertilization at fertility clinics in America? Dr.——

Dr. PRENTICE. I've been troubled by it, Senator——

Senator WYDEN. I'd like a yes——

Dr. PRENTICE.—because of the manipulation——

Senator WYDEN.—I'd like a yes or no answer, because I was really pretty floored by the answer I got, you know, earlier, because I had not, you know, heard that from Dr. Doerflinger. I had thought that he would not be opposed, that there would be some questions with respect to what would be done with the embryos. And that's something that I'm interested in. But just a yes or no answer. I mean, this is important, because millions of couples have found happiness through a specific procedure, IVF. Millions of couples. And I like to think that I played an itty-bitty part in it because I wrote the one law that makes it possible for couples to have some real protections, in terms of how they use it. Do you, or do you not, favor IVF as a procedure?

Dr. PRENTICE. As you've expressed it, yes, I favor IVF. But I would like, Senator, to see you write some more laws so that they're not making so many embryos that end up in the freezer. In Germany, there are 40, total.

Senator WYDEN. Well, the Chairman and I have talked about, Dr. Kass and others, have talked talk about ways in which we might update the law, but I appreciate your answer and appreciate your candor.

Dr. Daley, a couple of questions for you, if I could. There are a wide range of funds, including Federal funding for adult stem cell research. And it's been the view of Dr. Prentice and others having, you know, reservations about the value of embryonic stem cell research. Now, embryonic stem cell research, of course, faces restrictions on Federal funding, as opposed to adult stem cell research.

Do you think, therefore, that it is fair to compare the two—adult stem cell research and embryonic stem cell research, in terms of the progress, given the fact that there are restrictions with respect to embryonic stem cell research that there aren't with adult stem cells?

Dr. DALEY. Even without regard to the restriction, I think it's unfair to say that adult stem cells are doing so much better than embryonic stem cells that it justifies putting more emphasis behind adult stem cells.

Really, adult stem cells—and we're talking primarily about bone-marrow stem cells—have been studied, really, more like 50 or 60 years; whereas, human embryonic stem cells were first published 6 years ago. You're talking about a tenfold difference in time. You know, I mean, I think if you gave me a 50 year head-start in a bicycle race, I'd probably beat Lance Armstrong, too.

The fact is that human ES cell research is a fledgling field just getting off the ground. It has enormous promise, not solely for its therapeutic potential, the ability to actually move cells into patients, but these are enormously valuable tools for research. So you have to give us time to let the field mature.

Senator WYDEN. One other question for you, Dr. Daley, with respect to the practice of scientists. And I think you heard me earlier express—you know, my concern is that I think we're just, sort of, headed for a kind of crazy quilt of standards with respect to ethical practices, at a minimum. And I think it stems from the restrictions on Federal funding. And Dr. Doerflinger and others have different views on that, and I respect it.

My question to you would be, If there were Federal guidelines coupled with the availability of Federal funds for embryonic stem cell research for the new lines, the new areas that are so promising, wouldn't those guidelines essentially become an industry-wide standard at this point?

Dr. DALEY. I would hope so. I can't answer the specific legal aspects of how the Federal guidelines would ultimately compete with a patchwork quilt of guidelines on the level of the states. But I think we, as scientists, are very much looking to the Federal Government for leadership on this issue. It would make it a lot easier.

The cloud——

Senator WYDEN. Wouldn't it be—on that point, wouldn't it be in the interest of scientists and industry and all concerned if we tried to get to the point where we're sensitive to these ethical, you know, concerns? I want to emphasize, I want to do that, but we want to do it I in a clear kind of fashion. And wouldn't the kind of straightforward Federal role facilitate that kind of sensitivity throughout the field?

Dr. DALEY. There's no doubt that, since the NIH is really the lifeblood of funding for most of American science, that something done at the Federal level, under the auspices of the NIH, would certainly clarify the goals and mission of this field.

Senator WYDEN. My time is up. Just on this one point, Mr. Chairman.

See, what I'm concerned about is, almost everybody that I talk to in this field, regardless of their, you know, point of view, will usually say, "I want a win-win. I want the research done, I want

to help people who are suffering, and I want to be sensitive to ethics." Now, nobody wants to just go out and say, "There are no ethical concerns here," because there very obviously are.

My concern is that what's going to happen in this country, in terms of the direction we're going, instead of getting the win-win, we're going to have a lose-lose, we're not going to tap all the opportunities for research. And I think I documented what's happening in that regard. We're not using the available stem cell lines, even from the earlier plan of the President, nor are we using the new lines. And we're going to cause a significant amount of confusion with respect to what the ethical strictures are that we all want to have.

So instead of the win-win that, I think, virtually everybody, regardless of their point of view on this issue wants to have, I think if we don't get a clearly defined Federal role and have necessary Federal funding, instead of the win-win and the kind of opportunities for our country to provide the leadership role that we have the potential to play, we're going to have more of what I would characterize as a lose-lose. And I think that's regrettable, and I think Dr. Daley essentially agrees, and I suspect your two colleagues at the table would see that differently.

But, Mr. Chairman, I'm going to have to take off. But I think it's been a good hearing, and I thank you again for your fairness, in terms of how you approach all of this.

Senator BROWNBACK. Well, thank you for participating in it.

I do want to note, though, where you would see a lose-lose in this situation, we have patients who are being treated now with stem cell therapies, that are being cured. I've had them in here testifying—sickle cell anemia, something you'd be familiar with, Dr. Daley, umbilical cord blood transfusion, two ladies, Susan Fite—and other spinal cord injuries that are walking now—using canes, full body feeling, but walking—with adult stem cell therapy. We give heart transplant patients—I mean, I'd hardly say—call that a lose-lose in this situation. I respect how you're looking at it, but this thing is really moving forward.

And, Dr. Daley, as well, in your work, you are receiving NIH money to do stem cell research, umbilical—or, I mean, excuse me, embryonic and adult. So, I mean, you are receiving Federal dollars to do embryonic stem cell research. That's happening. And I understand your desire to expand the lines, but there is no private limitation at all, there is no limitation on any funding, there's no limitation on, for that matter, human cloning in this country. So the notion that—you know, that we've got this big clamp down at the Federal Government, I don't think is accurate. I think you really have to look at what is being limited is, you can use the Federal dollars on a set of lines that are developed. That's the limitation.

And I would put into the record a *Wall Street Journal* article of August 12, 2004, on the politics—the political science, they say, of stem cells. They document FY 2002, $521.1 million being spent on all forms of stem cell research. I can't think there's any country in the world with anywhere close to that spending level, and that includes embryonic, human non-embryonic, nonhuman embryonic, and nonhuman non-embryonic. So you've got both adult and embry-

onic in the whole field, but over a half billion dollars on an annual basis.

[The information referred to follows:]

The Wall Street Journal (on-line edition)—REVIEW & OUTLOOK—August 12, 2004

THE (POLITICAL) SCIENCE OF STEMS

You might not know about it from listening to the news lately, [but] the President also looks forward to medical breakthroughs that may arise from stem cell research. Few people know that George W. Bush is the only President to ever authorize Federal funding for embryonic stem cell research.—Laura Bush

The First Lady was way too polite: The way stem cells have been reported, you'd think we were in a new Dark Ages, with government-backed religious inquisitors threatening scientists on the cusp of life-saving treatments.

Reinforcing this misimpression are the headlines and commentators talking up a "ban" on research. "First lady Laura Bush defends ban on stem cell research" is how the Philadelphia Inquirer spun Mrs. Bush's talk. A sampling of other headlines shows the Inquirer is far from alone: "Rethink the stem cell ban" (Des Moines Register); "Stem cell ban stays, despite Reagan pleas" (Newark Star-Ledger); "Kerry says he'd reverse stem cell ban" (The Grand Rapids Press); "Kerry 'would lift stem cell ban'" (BBC), and on and on. You get the drift.

The problem is that the drift is wrong. As Mrs. Bush gently reminded her audience in Pennsylvania this week, far from banning embryonic stem cell research, George W. Bush is the first President to expand Federal funding for it. The nearby table shows that, as a result of his decision, Federal funding went from zero in 2000 to nearly $25 million today—and this doesn't include the many tens of millions more being spent by the private sector. As Health and Human Services Secretary Tommy Thompson points out, the supply of embryonic stem cell shipments available is today greater than the demand.

In other words, this is not, as Ron Reagan characterized it during his prime time slot at the Democratic convention, a battle between "reason and ignorance." It's an argument about taxpayer money and how to draw the lines around it.

WHAT FUNDING BAN?

Amount spent by the National Institutes of Health on stem cell research, in millions

	2001	2002	2003
Human Embryonic	$0.0	$10.7	$24.8
Human Non-Embryonic	151.6	170.9	190.7
Non-Human Embryonic	40.5	71.5	113.5
Non-Human Non-Embryonic	113.9	134.0	192.1
Total	306.0	387.1	521.1

Source: Office of Management and Budget

On the whole this would be a healthy debate for America to have. But the Kerry campaign seems more interested in politicizing the issue by continuing to advance claims for a ban that simply does not exist. Typical was the press release by the

campaign Website this week entitled "Edwards Calls for an End to Stem Cell Ban and a Return to Scientific Excellence in America." This is no slip: It's the same language Mr. Kerry used in his radio address when he declared he intends to "lift the ban on stem cell research." And it's the same language Hillary Clinton used during her own convention speech, drawing cheers when she invoked the "need to lift the ban on stem cell research."

All these people know better. The issue is Federal subsidies. The need for a Presidential decision arose from an appropriations rider passed by Congress in the mid-1990s forbidding Federal funding for any research that creates, injures or destroys human embryos.

The President's answer was that there ought to be no restrictions on the private sector but that Federal subsidies should be limited to lines that had already been harvested and should not be used to encourage the destruction of embryos. In short, it was a reasonable middle ground. It's worth noting that other countries, such as Germany, Ireland and Austria, ban even the private sector from creating embryos for stem cell research.

The potential for embryonic stem cells is that they are malleable and can differentiate themselves into needed cells. That gives them tremendous potential, but it also presents a liability because we can't yet control what these cells will turn into. In one animal study, a fifth of the mice injected with embryonic stem cells developed brain tumors.

Which helps explain why we still have not had a single human trial for embryonic stem cells. And it means that political claims that cures for diabetes or Parkinson's are just around the corner are cruelly raising false hopes.

Meanwhile there is another alternative we don't hear much about in the headlines: adult stem cells. Unlike embryonic research, adult stem cells do not get us into questions about the destruction of human life. In addition, a report in the journal Nature this summer suggests that adult stem cells may have a broader differentiation potential than previously thought.

Plainly this is one of those subjects that involves clashes of goods, in this case the sanctity of human life versus the needs of scientific research. The best way to resolve the issue of taxpayer funding is to let the American people make that decision themselves, through their elected representatives. And dealing, we hope, with the science—not just the Kerry campaign sound bites.

Senator BROWNBACK. So we're investing heavily in this field, and finding some beautiful science out. I understand you don't have—share quite the ethical concern I do for the——

Dr. DALEY. We always need more resources. There's—there are——

Senator WYDEN. Mr. Chairman?

Dr. DALEY.—this is among the most exciting new areas of biology. I can tell you that there's an interesting dynamic. On the one hand, you have the students who are so enormously excited, and they want to jump in; on the other, you have a lot of investigators who, because of the current cloud, the controversy, are staying on the sidelines. There's a very interesting dynamic going on.

Senator WYDEN. Mr. Chairman, can I——

Senator BROWNBACK. Let me——

Senator WYDEN.—can I just make a unanimous consent request, in terms of the battle between newspaper articles?

[Laughter.]

Senator BROWNBACK. You can, but I want to finish with my battle on this, and then I'll be happy to take that one from you.

There's no country in the world that's investing heavier in stem cell research than the United States, is there, Dr. Daley?

Dr. DALEY. Actually, I don't know, but I don't imagine there's any country in the world that enjoys the level of support that the United States does for basic biomedical research, and I am thankful for that, and I think it's one of the greatest gifts of our Federal Government to our society.

Senator BROWNBACK. Well, and we've doubled, under a Republican Congress—and Senator Wyden supported it—NIH funding over the past 5 years, 6 years. I think most of us view that as an excellent investment in research. Stem cell funding has benefited from that.

So I just—I want to get this honed down a little bit. When we talk about all these restrictions on it, at the end of the day it's bout the level of the lines, and the funding has been far and away above what any other country in the world is doing in this area.

So now if you want to put your—I want to ask unanimous consent mine be put in the record, and yours will be accepted, as well.

[The articles referred to are reprinted on pp. 3–4 of this hearing record.]

Senator WYDEN. I thank you, Mr. Chairman. I just think it's important. I would just ask unanimous consent that the two articles that have been discussed be placed side by side, because the one that my friend, the Chairman, is talking about essentially offers an opinion piece, but the—because I have read that, and I respect the Wall Street editorial writers on this point—but the facts are, as documented in this article that I've asked to be put in the record, that only 21 of the initial 78 stem cell lines are available to researchers today, number one; and scientists say that more than a hundred new lines have been developed since the cutoff date of the President, and that some of those are better suited for research. That is essentially a direct quote out of the article that will be in the record in the battle of the newspaper articles.

And just, since the Chairman's being very kind to me, I only say that I acknowledge—and, Dr. Prentice, I think you might have been here when we talked earlier about adult stem cells—there's no question that people have been helped with adult stem cells. And more power to it. I am for it. What I am concerned about is the potential for the field, and that's what I have characterized is, unfortunately, headed toward instead of the, kind of, win-win that everybody at this table, you know, appropriately and sincerely wants—but in terms of the potential, we don't get what we ought to have, in terms of the ethical standards, nor do we get what's—in terms of the potential for the research.

But this debate will continue with the usual level of thoughtfulness that Senator Brownback brings to this Committee, and I look forward to it.

Senator BROWNBACK. Thank you very much.

Dr. Daley, in the scientific community, you've got a—amongst your colleagues when you're meeting, you've got to talk about this issue a fair amount. And I'm sure there's a great deal of frustration, because I get it in the testimony, people coming up and testifying. But you have to—I presume you must be debating, as well, When is there moral significance to the youngest of humans? And you would agree, biologically, you became your person—you became your life when that union and fertilization occurred, biologically. You can just debate the theological position, but, biologically, you became genetically you at the moment of fertilization, biologically. That would be accurate, wouldn't it?

Dr. DALEY. I mean, yes, of course.

Senator BROWNBACK. So when scientific—when you—just in talking with your colleagues, or talking about, "Well, OK, yes, obviously I was biologically me at the moment of conception," but I don't want to—I'm so—there's so much promise here, I want to set the date at this point in time, before we really attach moral significance to—what is this date that you would then attach, when you talk with your colleagues, moral significance to the youngest of humans?

Dr. DALEY. Honestly, I don't think any scientist can draw a line for you at when moral significance is endowed in the period of human development. It is not a line. But I think that we are all comfortable with the idea of using the earliest microscopic ball of cells in our research.

From a biologist's perspective, life is, indeed, a continuum. We are all, in some way, shape, or form, descended from our original ancestors—Adam, Eve. Cells are immortal in the sense that through our line, we pass on life to our kids. I am mortal as a being, but, in seeing my children, I realize that we, as a species, are immortal. Life is in every cell. Every cell has the potential to give forth life. So these arguments about trying to get us to say, "When does life begin," I think, is really defined in the realm of theology and the realm of things beyond biology.

Senator BROWNBACK. Well, you make it difficult for us, then, because, at some point in time, you gained moral significance. And you talked about teaching your boys baseball, which is such a pleasurable thing. And, at some point in time, they gained moral significance to you. Have you thought about when that line was?

Dr. DALEY. I'm really challenged by it. Yes. I'll tell you when I think about it. I think about it when I'm called to consult in our neonatal intensive-care unit—that's when I'm thinking about it—and you're seeing these tiny little premature babies, and it really calls into question, When is it that that life can exist independent of all of our technology? And when is it that you can actually hug that child and feel that it has significance?

You know, I—when I—I can't hug an embryo. I just can't see it as morally equivalent to my kids and my patients. And my mission in stem cell research is aimed more at serving their needs.

Senator BROWNBACK. But you would agree, if your children were researched on at the blastocyst stage, they wouldn't be here.

Dr. DALEY. Yes.

Senator BROWNBACK. Nor would you, nor would I, at that point in time. And you're not willing to set for me, "OK, at this point in time, moral significance begins to the"—and you and your colleagues don't particularly, I guess, discuss when this line is. You see the promise of the research, and you're looking—and I applaud your heart of, "I want to cure people," because I want to cure people, too, and I'm glad you've got that heart. But you don't discuss about, "OK, we would really put moral significance at this point in time, or that."

Dr. DALEY. I think that there would be consensus among biologists that it would be impossible to define that time. There are definitions that, say, the British have assigned, through the Human Fertilization and Embryo Authority, which are convenient biological timelines, and the definition would be 14 days, for in-

stance, with a human embryo, which is about the time that the primitive streak forms, the earliest specialization of the embryo into the different tissue types. That's a matter of convenience. I don't think one is defining 14 days as the point of moral significance; it just does allow us to say—certainly before that time, very few people would argue; after that time, I think it's impossible.

Senator BROWNBACK. All right, that's fair enough. I just—I would hope that your colleagues, as you discuss in your cell biology organization and others, would, you know, discuss about—this is a major issue. You obviously wouldn't want to research on somebody that's a full blown human being. You wouldn't want research on your children or yourself. You wouldn't want it on me, on my children. OK, we accept that. Then where can we, then, start researching on you without your permission? At what age?

Dr. DALEY. Right. I invite your opinion, as well as everyone else, to engage in that discussion. I don't think it's at the age of the blastocyst, however.

Senator BROWNBACK. But you're not willing to establish when I think this would or should——

Dr. DALEY. No. No. Sorry.

Senator BROWNBACK. All right, fair enough.

Gentlemen, thank you very much. It's very illuminating. I'm delighted to hear about the potential for the use of fat. We have plenty of it in America. We have this huge obesity problem, and I'm hopeful for the day when we can use it to solve many of our maladies. The hearing's been excellent.

The hearing's adjourned.

[Whereupon, at 4:30 p.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF FRANK R. LAUTENBERG,
U.S. SENATOR FROM NEW JERSEY

Mr. Chairman:

This hearing is entitled "Embryonic Stem Cell Research: Exploring the Controversy." Frankly, if you ask me, there is no controversy here. Embryonic stem cell research is critical to our mission to fight and cure disease in this country.

The debate over whether we should pursue adult stem cell research or embryonic stem cell research sets up a false choice.

Both types of stem cell research should be pursued simultaneously. Each type of research offers the potential for cures; neither is a substitute for the other. No promising stem cell research should be stopped. The National Academy of Sciences has said as much.

Stem cell research, particularly the burgeoning field of embryonic stem cell research, has tremendous potential to help up better understand, treat, and even cure deadly and disabling diseases like diabetes, cancer, Parkinson's Alzheimer's and multiple sclerosis. Stem cell research could help us cut the incidence of heart disease, the Nation's leading killer.

Most American support embryonic stem cell research. Significantly, by a margin of 54 percent to 29 percent, Catholics support such research, according to a recent survey by Peter D. Hart Research Associates. The survey also indicated that the more people learn about the issue, the more they are inclined to support the research. I ask unanimous consent that the survey results appear in the hearing record following my statement.

Members of Congress from both sides of the political aisle support the research, including our "pro-life" colleague, Senator Hatch, who stated that "life begins in the womb, not in a petri dish."

Forty Nobel Laureates also support the research, as does former First Lady Nancy Reagan who spent ten years watching her husband suffer from Alzheimer's disease.

Virtually every major medical, scientific, and patients' advocacy group supports embryonic stem cell research. I'm talking about the American Medical Association, the Federation of American Societies for Experimental Biology, the Juvenile Diabetes Research Foundation, and the Parkinson's Action Network.

In my view, President Bush's stem cell research policy sacrifices sound science in favor of policy expediency. His policy is, in effect, denying tens of millions of people suffering from physically and mentally debilitating diseases, illnesses, and injuries from being cured.

First Lady Laura Bush recently said, "We don't even know that stem cell research will provide cures for anything—much less that it's very close" to yielding major advances.

What the First Lady is saying, in effect, is that because we don't know what the research will yield—and because it will take a long time—we shouldn't bother starting it. With all due respect, scientists disagree and that's not the sort of attitude that leads to scientific breakthroughs that improve life.

I appreciate the sincerity of the views of those who oppose embryonic stem cell research, but I have met with too many diabetic children and their families. I have seen how they suffer and I simply cannot tell these children or their parents that in the hierarchy of rights, a week-old undifferentiated cell is more important than they are and cannot be used in research, treating, or possibly curing their terrible disease.

The millions of men, women, and children who are suffering from diabetes and other life threatening diseases, illnesses, and injuries are engaged in a race against time. It is our responsibility to make sure that they and future generations benefit as quickly as possible from the wonders of modern science, medicine, and technology have to offer.

Thank you, Mr. Chairman.

VOTERS' VIEWS ON STEM CELL RESEARCH

Prepared by Peter D. Hart Research Associates for the Civil Society Institute—March 2004

Introduction

From March 24 to 29, 2004, Peter D. Hart Research Associates conducted a telephone survey on behalf of the Civil Society Institute. This survey was conducted among registered voters in 18 states and was designed to explore public opinion on Federal funding for stem cell research. The states included were Ohio, Michigan, Pennsylvania, Maine, New Hampshire, Wisconsin, Minnesota, Iowa, Washington, Oregon, New Mexico, Nevada, Arizona, Florida, Louisiana, Arkansas, Missouri, and West Virginia. With 802 interviews, the margin of error for this survey is ±3.5 percent, with larger margins of error for subgroups.

Knowledge and Impact of Stem Cell Issue

Public knowledge of stem cell research has increased over the past few years. Three in four (76 percent) voters say that they have heard a lot or a little about medical research involving embryonic stem cells, up from 69 percent of voters nationally in August 2001.[1] Nearly one-third (31 percent) of voters affirm hearing a lot, an increase from August 2001 when 25 percent claimed the same level of knowledge about stem cell research.

Nearly all have a personal connection to the issue. Nearly every (86 percent) voter reports having a family member or close friend who potentially could benefit from stem cell research. More than two-thirds (68 percent) have some experience with cancer, and more than half (58 percent) have been affected by heart disease. Aside from these two more widespread diseases, 49 percent of voters report having a close personal friend or family member who has suffered from Alzheimer's disease, Parkinson's disease, juvenile diabetes, or spinal cord injury—and thus could be affected by medical research on stem cells.

Voters strongly support Federal funding for medical research. Even when compared with other items such as national defense, transportation, or education, 59 percent of voters say that Federal funding for medical research should be a high priority, including 31 percent who say that it should be a very high priority. Another 35 percent say that funding for medical research should be a moderate priority. Just 6 percent do not see medical research funding as a priority for the Federal government. Support is higher among Democrats (64 percent) than among Republicans (46 percent), and is highest among the politically important independents (67 percent).

A majority of voters in these states support embryonic stem cell research.—Overall, voters favor stem cell research by 53 percent to 30 percent. This is an increase in support from the August 2001 survey, when voters nationwide expressed support for embryonic stem cell research by only 48 percent to 43 percent.

Democrats and Republicans offer different views on embryonic stem cell research (in the demographics portion of the survey, voters were asked whether they would describe their overall point of view in terms of the political parties as Democratic, Republican, or completely independent). Democrats favor stem cell research by a 46-point margin (65 percent to 19 percent), whereas Republicans oppose stem cell research by a nine-point margin (47 percent to 38 percent). However, independents have a view that is much closer to Democrats' than Republicans', as independent voters favor stem cell research by a 32-point margin (55 percent to 23 percent). In political terms, the center of the electorate clearly embraces the importance of stem cell research.

[1] Virginia Commonwealth University survey, conducted 8/29–9/2/01; surveyed 1,122 adults nationwide; margin of error ±3 percent (release, 10/4/01).

INITIAL VIEW OF STEM CELL RESEARCH AMONG KEY SUBGROUPS

	Favor %	Oppose %	Margin In Favor %
All Voters	*53*	*30*	*+23*
Men	53	30	+23
Women	53	30	+23
Ages 18-39	52	28	+24
Ages 40-59	57	28	+29
Ages 60 and over	49	34	+15
Non-college educated	48	33	+15
4-year college grads	56	27	+29
Postgraduates	74	20	+54
Mainline Protestants	59	23	+36
Evangelicals	34	53	-19
Catholics	54	29	+25
Democrats	65	19	+46
Independents	55	23	+32
Republicans	38	47	-9

Support increases with education level, as 63 percent of college graduates favor stem cell research compared with 48 percent of non-college voters who say the same. Support is even higher among those with a postgraduate degree: nearly three in four (74 percent) say that they strongly or somewhat support embryonic stem cell research. Along gender lines, support is equal among men (53 percent) and women (53 percent). College men (61 percent) are much more likely than are non-college men (49 percent) to favor stem cell research, and the education gap is even greater among women, with 65 percent of college women and just 47 percent of non-college women favoring stem cell research.

Dividing the states into regions shows that a majority of voters in the West (60 percent), rural Midwest (54 percent), Northeast (52 percent), and South (52 percent) support stem cell research, along with a large plurality in the industrial Midwest (49 percent). Religion is another strong predictor of voters' views on stem cell research. As expected, support is low among Evangelical Protestants (34 percent) but much stronger among mainline Protestants (59 percent). Significantly, Catholics (54 percent) support stem cell research nearly as strongly as the mainline Protestants.

Analysis also reveals that the more people have heard about the issue, the more they support stem cell research. Voters who say that they know a lot about the issue support stem cell research by 68 percent to 26 percent, whereas voters who say that they know little about the issue support it by a much smaller 36 percent to 30 percent.

Support grows with more information. Support for embryonic stem cell research increases 13 percentage points to 66 percent when people are informed that couples are donating unwanted embryos that otherwise would be discarded. After hearing a more detailed description of embryonic stem cell research and the diseases it can help cure, support grows even more. Overall, three in four (76 percent) voters support stem cell research after hearing the following description:

> Embryonic stem cells are special cells that can develop into every type of cell in the human body. The stem cells are extracted from frozen embryos in fertility clinics, donated by couples who no longer want or need the embryo. This process destroys the embryo. These stem cells can then reproduce on their own, creating what is called a "line" of stem cells that many researchers can work with. Scientists believe that there is a good chance that stem cells can be developed into

cures or treatments for diseases such as cancer, Parkinson's, Alzheimer's, juvenile diabetes, and spinal cord injuries.

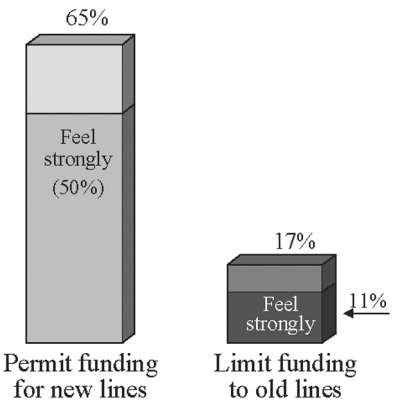
Clearly, the potential of stem cell research to produce treatments for a wide range of diseases and conditions is a very powerful consideration for voters. Even subgroups originally resistant to the idea, such as Evangelicals and Republicans, support stem cell research after hearing a description of the process and potential of the research, despite the explicit recognition of the embryo destruction required.

A large majority of voters in these states would change the Bush Administration's August 2001 policy restricting embryonic stem cell research.—More than two-thirds (68 percent) of voters support the three longstanding criteria for Federal government funding of stem cell research: (1) the cells must come from an embryo that was created for reproductive purposes and is no longer needed, (2) researchers must obtain the consent of the couple donating the embryo, and (3) the donors cannot be paid for use of the embryo.

In August 2001, the Bush Administration established a new restriction on Federal funding for embryonic stem cell research. This restriction says that research on stem cell lines created before August 2001 can receive funding, but funding is prohibited for research on stem cell lines developed after that date. However, the survey results reveal that voters overwhelmingly oppose this restriction and favor funding for research using newer stem cell lines. Fully 65 percent support expanding Federal government funding for stem cell lines created after August 2001, including 50 percent who feel strongly, compared with only 17 percent who support maintaining the Bush Administration's August 2001 restrictions.

Majority Wants To Change Bush Administration Policy

Should federal funding for stem cell research be limited only to stem cell lines created before August 2001 (Bush administration restriction), or should funding be permitted for newer stem cell lines that meet other federal ethics regulations?



Key political groups, such as independents and persuadable voters, strongly support a policy allowing Federal funding for research on newer stem cell lines. As the accompanying table shows, the August 2001 restrictions garner relatively little support even among groups not favorable to stem cell research initially, such as Republicans, Evangelicals, and conservatives.

FEDERAL FUNDING SHOULD BE...			
	Permitted For New Cell Lines	Limited To Old Cell Lines	Margin For New Policy
	%	%	%
All Voters	*65*	*17*	*+48*
Men	63	20	+43
Women	67	13	+54
Ages 18-39	66	16	+50
Ages 40-59	67	18	+49
Ages 60 and over	62	14	+48
Mainline Protestants	69	13	+56
Evangelicals	46	30	+16
Catholics	70	15	+55
Democrats	78	10	+68
Independents	70	11	+59
Republicans	47	27	+20
Liberals	65	17	+48
Moderates	80	9	+71
Conservatives	44	28	+16

It is important to note that strong majorities of voters disagree with the two primary justifications for the August 2001 restriction: 1) that there are enough stem cell lines that were created before August 2001 to support research needs, and 2) that the government should not create an incentive to destroy more embryos by funding research on them.

On the topic of the number of viable stem cell lines available for research, voters were read statements from both supporters and opponents of the Bush Administration's August 2001 policy and were asked which statement they agree with more.

> *Statement A: People who support the Bush Administration's policy say that there already are sufficient embryonic stem cell lines to meet the needs of researchers. The Bush Administration's policy will allow stem cell research to move forward and help cure diseases, without violating our ethical standards by supporting the destruction of additional embryos.*
>
> *Statement B: People who support funding for research using newer stem cell lines point out that when the Bush Administration's policy was created, people thought there were at least seventy stem cell lines available for research. But it turns out there are only fifteen lines available, and almost all researchers agree that many more are needed for stem cell research to fulfill its promise. Given these new facts, we need a new policy that allows life-saving research to proceed.*

Again, after hearing statements from both sides of the debate, a large majority (65 percent) agree with those who favor expanded funding for newer stem cell lines, with 49 percent who feel strongly. Fewer than one in four voters (23 percent) agree that funding should be limited to the old stem cell lines, including 16 percent who feel strongly.

On the topic of destruction of embryos, voters again were presented with statements from opponents and supporters of expanding Federal funding for use in research on newer stem cell lines, and were asked which statement they agree with more.

Statement A: People who support the Bush Administration's policy say that funding for the old stem cell lines is right because those embryos already had been destroyed, but if funding is made available for research on newer stem cell lines it will create an incentive for the destruction of additional embryos. They say it is wrong for the government to support or encourage the destruction of human embryos.

Statement B: People who support Federal funding for research using newer stem cell lines say these newer stem cells will come from embryos in fertility clinics that are voluntarily donated by couples who no longer need or want them and they likely will be discarded. They say there are already tens of thousands of such frozen embryos that will be discarded by their donors if they are not used for research. It only makes sense to use these embryos to cure diseases and save lives.

Again, by a more than two to one, voters solidly agree with supporters of Federal funding on newer stem cell lines, as 66 percent of voters say that they agree with the supporters of expanded Federal funding, including 51 percent who strongly agree. On the other side of the coin, just 24 percent agree that funding should be limited to the old stem cell lines, including 18 percent who feel strongly.

Voters in these states are more persuaded by arguments in favor of allowing research than by arguments in favor of the August 2001 restriction.—The survey presented voters with the strongest arguments made by both sides of the stem cell debate. The most persuasive argument tested in favor of the Bush Administration's policy of limited funding for stem cell research is that there should be more comprehensive research on stem cell lines from adults, umbilical cords, and animals to gauge their usefulness before more embryos are destroyed. Half (50 percent) of voters find this argument very or fairly convincing, and a nearly equal proportion (47 percent) say that it is just somewhat or not at all convincing. Other arguments in favor of the administration's policy—that embryonic stem cell research is immoral, that it is possibly unethical, that it is exploitative of a human life—generally prove less persuasive to voters.

Reasons to Support the Bush Administration's Policy

(Proportion saying each is a very/fairly convincing reason)

50%	In addition to embryonic stem cell lines, there are many stem cell lines available to researchers that come from adult humans, umbilical cords that are discarded after birth, and animals. We should first see whether these stem cells can provide the cures and treatments we need, before destroying more human embryos.
43%	Under the current policy, there already are sufficient stem cell lines available for researchers to begin exploring the potential of stem cell research. We do not know yet whether additional stem cell lines are needed, and until we do, we should maintain the strongest protections possible against exploitation of human life.
35%	For the sake of moral principle and human dignity, it is time that we draw the line. Banning Federal government funding for research on newer stem cell lines is a good way to make sure that embryos are not created and destroyed for research purposes.
32%	Pro-life organizations believe that it is immoral to destroy living human embryos, even for medical research.
32%	Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life. It is wrong to provide taxpayer funding to research that sanctions and encourages the future destruction of human embryos.
30%	There is no such thing as an excess life, and the fact that a living embryo is going to be discarded does not justify experimenting on it or exploiting it as a natural resource.

Voters agree more with arguments for allowing research on newer stem cell lines. The most convincing argument is that embryonic stem cell research is similar to organ donation in that neither organ donors nor frozen embryos will live and that there is a great medical need for both (69 percent very/fairly convincing). Two-thirds (65 percent) of voters agree that our government should support rather than stand in the way of research that will help ease the suffering of more than 100 million Americans who are suffering from diabetes, Alzheimer's, Parkinson's, and other diseases and conditions.

Reasons to Fund Research on Newer Cell Lines

(Proportion saying each is a very/fairly convincing reason)

69%	This issue is very similar to organ donation. Neither frozen embryos nor organ donors are going to live, and in both cases there is an urgent medical need that can be filled by the donation of needed tissue. Just like organ donation, stem cell research can save millions of lives.
65%	Stem cell research offers the best hope we have today for curing such diseases as Alzheimer's, diabetes, heart disease, and cancer, which today cause pain and suffering to more than 100 million Americans. Our government should be fully supporting this research, not standing in the way.
63%	Currently fertilization clinics in the United States have tens of thousands of embryos that have been donated by couples who no longer need or want them. If these embryos cannot be used in stem cell research, they will simply be discarded by the donors, and no benefits at all will be derived from them.
63%	Highly respected organizations such as the AMA, National Academy of Sciences, National Institutes of Health, Juvenile Diabetes Research Foundation, and Alzheimer's Association strongly support allowing research on newer stem cell lines.
58%	Nancy Reagan, Michael J. Fox, and Christopher Reeve all support funding for research on newer stem cell lines, because they know it represents the best chance we have to prevent suffering from Alzheimer's, Parkinson's disease, spinal cord injuries, and other afflictions.
56%	When the Bush Administration's policy was established, it was believed that there were 78 stem cell lines available for research. But it turns out there are only 15 lines that meet the Bush Administration's conditions, and researchers agree that many more are needed to move forward with meaningful stem cell research.

Sixty-three percent of voters are convinced by the argument that if embryos that donors no longer need are not used for research, fertility clinics will simply discard them with no benefit to medical research. An equal proportion find the support of the American Medical Association, the National Academy of Science, National Institutes of Health, the Juvenile Diabetes Research Foundation, and the Alzheimer's Association of research on new stem cell lines a convincing reason to lift the August 2001 restrictions on Federal funding.

Many supporters of changing the August 2001 restriction are seen as highly trustworthy sources of information on the issue of stem cell research.—Two-thirds or more of voters say that they trust the information provided by a number of stem cell research supporters, including 87 percent who say they trust information from health organizations such as the American Medical Association and the Alzheimer's Association. Additionally, the opinions of celebrities who favor funding for newer cell lines, such as Mary Tyler Moore (75 percent), chairwoman of the Juvenile Diabetes Research Foundation; Christopher Reeve (73 percent), founder of the Christopher Reeve Paralysis Foundation; Michael J. Fox (67 percent), founder of the Michael J. Fox Parkinson's Research Foundation; and Nancy Reagan (65 percent) are considered trustworthy. These findings indicate that not only do the arguments in favor of expanded stem cell research resonate strongly with voters, they also consider the individuals and organizations making these arguments to be highly credible.

After hearing arguments from both sides, support for research on new cell lines remains high.—Total support climbs four percentage points to 69 percent, and strong support increases eight points to 58 percent, whereas support for the 2001 Bush Administration's policy is just 20 percent. Clearly, voters broadly favor dropping the August 2001 Bush Administration restrictions and allowing research funding to include using newer stem cell lines. Further debate is likely to strengthen, not weaken, that consensus.

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